DEPARTMENT OF DEFENSE

FISCAL YEAR 2002
BREAST CANCER RESEARCH PROGRAM
PROGRAM ANNOUNCEMENT II

March 13, 2002

Headquarters, U.S. Army Medical Research and Materiel Command
MCMR-PLF, 1077 Patchel Street
Fort Detrick, Maryland 21702-5024

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Foreword

The U.S. Army Medical Research and Materiel Command (USAMRMC) has been directed to continue the Department of Defense (DOD) Breast Cancer Research Program (BCRP). The deadline, format, and other criteria specified for proposals in this DOD fiscal year 2002 (FY02) BCRP Program Announcement are based on program objectives, public needs, and regulatory guidance.

Specific information on the USAMRMC, U.S. Army Medical Research Acquisition Activity (USAMRAA), the Congressionally Directed Medical Research Programs (CDMRP), and the DOD BCRP can be obtained from the CDMRP web site at http://cdmrp.army.mil. A copy of this program announcement and associated forms also can be downloaded from the CDMRP web site (for information on completing the Proposal Information, see Section 7, page v of this Foreword and Appendix C).

1. Overview of the FY02 Program Announcements

- **Proposals for the FY02 BCRP will again be requested through the publication of two separate program announcements.**

- This program announcement (Program Announcement II) is requesting proposals in three new award mechanisms: Exploration, Physician-Scientist Training, and Clinical Research Nurse Training Awards, as well as five award mechanisms that have been offered in previous years: Idea, Undergraduate Summer Training Program, Predoctoral Traineeship, Postdoctoral Traineeship, and Innovator Awards. Program Announcement II can be downloaded from the CDMRP web site at http://cdmrp.army.mil; no printed copies are available from the CDMRP.
- Program Announcement I was released February 21, 2002 and requests proposals in five award mechanisms, all of which require submission of a pre-proposal. One is a new award mechanism: Biotechnology Clinical Partnership Awards, and four have been offered in previous years: Clinical Translational Research (CTR), Collaborative-CTR, Breast Cancer Center of Excellence, and Historically Black Colleges and Universities/Minority Institutions (HBCU/MI) Partnership Training Awards. Program Announcement I can be downloaded from the CDMRP web site at http://cdmrp.army.mil; no printed copies are available from the CDMRP.

2. Highlights of Changes from the FY01 Program Announcements

- The Exploration Award is a new award offered to fund an initial concept or theory (with no preliminary data) that could give rise to a testable hypothesis.

- Innovation will be the primary review criterion for the Exploration Awards and will receive increased emphasis in the evaluation of Idea Awards.

- The Clinical Research Nurse Award and Physician-Scientist Training Award are new mechanisms offered in this program announcement.

- For Undergraduate Summer Training Program Awards, the minimum number of students participating in the program has been increased from 2 to 4.

- An authorized Administrative Representative from the Sponsored Programs Office at the applicant's organization will be **required to submit one electronic version of the applicant's proposal as a Portable Document Format (PDF) file through the Internet (electronic submission)**; the electronic PDF file will serve as the official proposal submission. Applicants unfamiliar with the preparation and submission of PDF files are encouraged to acquire the software and learn the process before the submission deadline.

- Margins for proposal preparation and acceptance have been changed to a minimum of **0.5-inch top, bottom, right,** and **1-inch left**. The print area must not exceed **7.0 x 10.0 inches (approximately 19.0 cm x 25.5 cm)**.

- The paper Proposal Cover Booklet has been replaced by Proposal Information found online at http://cdmrp.org/proposals.

- The Certificate of Environmental Compliance and Principal Investigator Safety Program Assurance documents have been incorporated into Appendix B and are due with the proposal submission. Additional documents related to Regulatory Compliance and Quality issues (RCQ) will be available on the CDMRP web site by April 2002. You will be notified if you need to submit these additional RCQ documents to support your submission.

- All submissions to the BCRP that involve human subjects should provide medical care for research-related injuries at no cost to the subject. Investigators should plan on budgeting for such costs.

3. Who May Apply

Individuals, regardless of ethnicity, nationality, or citizenship status, may apply through an eligible institution. Eligible institutions include for-profit, non-profit, public, and private organizations. Examples include universities, colleges, hospitals, laboratories, companies, and agencies of local, state, and federal governments. Please refer to sections on individual mechanisms for additional eligibility criteria.

4. Submission Deadlines

The proposal submission deadline is different for each award mechanism. Please check the timelines below or the award mechanism of interest for more details. An electronic PDF version of your proposal, which will serve as the official proposal submission, must be sent through the Internet by an authorized Administrative Representative of the Sponsored Programs Office (or equivalent) of your organization no later than date and time specified for the particular award mechanism for which you are applying. See Appendix B, part 23, and Appendix C for additional details.

5. Timelines

a. The timeline for Idea Awards is:

Electronic Letter of Intent:	As soon as possible but no later than May 30, 2002.
Proposal Submission Deadline:	**One electronic PDF version** of the proposal must be sent through the Internet no later than **11:59 p.m. (applicant's local time) June 11, 2002.**
Peer Review:	August 2002
Request for RCQ Documents:	As early as 2 weeks after the completion of peer review
Programmatic Review:	November 2002
Notification:	Approximately 2 weeks after programmatic review
Award Date:	Between January 2002 and September 2003

b. The timeline for Undergraduate Summer Training Program, Predoctoral Traineeship, Postdoctoral Traineeship, Clinical Research Nurse, and Physician-Scientist Training Awards is:

Electronic Letter of Intent:	As soon as possible but no later than May 30, 2002.
Proposal Submission Deadline:	**One electronic PDF version** of the proposal must be sent through the Internet no later than **11:59 p.m. (applicant's local time) June 12, 2002.**
Peer Review:	August 2002
Request for RCQ Documents:	As early as 2 weeks after the completion of peer review
Programmatic Review:	November 2002
Notification:	Approximately 2 weeks after programmatic review
Award Date:	Between January 2002 and September 2003

c. The timeline for Exploration Awards is:

Electronic Letter of Intent:	As soon as possible but no later than May 30, 2002.
Proposal Submission Deadline:	**One electronic PDF version** of the proposal must be sent through the Internet no later than **11:59 p.m. (applicant's local time) June 13, 2002.**
Peer Review:	August 2002
Request for RCQ Documents:	As early as 2 weeks after the completion of peer review
Programmatic Review:	November 2002
Notification:	Approximately 2 weeks after programmatic review
Award Date:	Between January 2002 and September 2003

d. The timeline for Innovator Awards is:

Required Electronic Letter of Intent:	Submission ***required*** no later than **11:59 p.m. (applicant's local time) May 30, 2002.**
Proposal Submission Deadline:	**One electronic PDF version** of the proposal must be sent through the Internet no later than **11:59 p.m. (applicant's local time) June 13, 2002.**
Peer Review:	August 2002
Request for RCQ Documents:	As early as 2 weeks after the completion of peer review
Programmatic Review:	November 2002
Notification:	Approximately 2 weeks after programmatic review
Award Date:	Between January 2002 and September 2003

6. Inquiries

Questions concerning the proposal format or required documentation can be addressed to the CDMRP at:

Phone: 301-619-7079
Fax: 301-619-7792
E-mail: cdmrp.pa@det.amedd.army.mil
Mail: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (BCRP02)
1077 Patchel Street (Building 1077)
Fort Detrick, MD 21702-5024

Applicants should submit questions regarding this program announcement via e-mail or in writing as early as possible. Every effort will be made to answer questions within 5 working days of receipt.

Help lines will be available by May 7, 2002 to answer specific questions regarding the preparation of proposals for electronic submission or the process of electronic submission. The help line phone numbers will be provided on two web sites: the CDMRP web site (http://cdmrp.army.mil) and the proposal submission web site (http://cdmrp.org/proposals). Alternately, help can be obtained by e-mail at help-proposals-cdmrp@cdmrp.org.

7. Proposal Submission

Applicants should refer to sections on individual award mechanisms and Appendix B for appropriate submission requirements. Effective with this program cycle, electronic submission of proposals is required.

Proposals will be submitted electronically at http://cdmrp.org/proposals. The web site will be available for proposal submission by May 7, 2002. An authorized Administrative Representative from the Sponsored Programs Office of the applicant's organization must submit one electronic PDF version of the applicant's proposal, which will count as the official proposal submission.

Several steps are critical for successful electronic submission of the applicant's proposal:

a. The applicant is required to submit Proposal Information (referred to in previous years as the Proposal Cover Booklet) online at http://cdmrp.org/proposals to include the e-mail address of an Administrative Representative from the Sponsored Programs Office who is authorized to conduct negotiations on the applicant's behalf (see Appendix C). **The Proposal Information must be submitted prior to submission of the proposal. Applicants are encouraged to begin this part of the submission process early and submit their Proposal Information at least 2 weeks prior to the submission deadline.**

b. Once the applicant has submitted the Proposal Information, the Administrative Representative from the Sponsored Programs Office will receive an e-mail notification that the Proposal Information is ready for his or her review.

c. Applicants will need to provide the Administrative Representative with an electronic copy of the proposal. Applicants are encouraged to coordinate early with their Sponsored Programs Office.

d. The Administrative Representative is required to provide final approval of the Proposal Information and then to upload/submit the proposal file in PDF. Please note that the web site does not allow applicants to upload/submit their proposals directly. **Proposals may ONLY be uploaded/submitted by the Administrative Representative from the Sponsored Programs Office and this can be done ONLY after he or she has approved the Proposal Information.**

Please note that all proposals must be submitted electronically to this program; printed supplemental materials will not be accepted. Any supporting documentation that the applicant wishes to include with the proposal must be scanned and incorporated into the PDF file prior to upload/submission. The Proposal Information must be completed online and the PDF version of the proposal uploaded/submitted through the web site (http://cdmrp.org/proposals) no later than the date and time specified as the proposal submission deadline for the particular award mechanism for which you are applying (see pages iii-iv of this Foreword). Detailed instructions for electronic submissions will be available at http://cdmrp.org/proposals by May 7, 2002.

I. Overview of the Congressionally Directed Medical Research Programs

I-A. History of the Congressionally Directed Medical Research Programs

Due to increased public awareness, the success of the Department of Defense (DOD) Congressionally Directed Medical Research Programs (CDMRP), and the work of grassroots advocacy organizations, Congress has appropriated monies for peer reviewed research directed toward specific diseases. Beginning in fiscal year 1992, the U.S. Congress has directed the DOD to manage these various extra- and intramural grant programs. The U.S. Army Medical Research and Materiel Command (USAMRMC) established the CDMRP to administer these funds. To date, the USAMRMC CDMRP has received more than $2.2 billion targeted by Congress for peer reviewed research on breast cancer, prostate cancer, ovarian cancer, neurofibromatosis, Defense Women's Health, osteoporosis, and other specified areas.

The CDMRP exists to support research that will positively impact the health of all Americans. The CDMRP strives to identify gaps in funding and provide opportunities that will enhance program research objectives without duplicating existing funding. To meet these goals, the CDMRP has developed unique mechanisms to facilitate the funding of quality research that addresses individual program objectives.

I-B. Investment Strategy

For each program, the CDMRP has developed and refined a flexible execution and management cycle that spans the development of an investment strategy through the completion of research. A Program Staff, composed of military and civilian scientists and clinicians, manages the CDMRP. For each program, an expert Integration Panel (IP) of scientists, clinicians, and consumer advocates is convened to deliberate issues and concerns unique to the program, establish an appropriate investment strategy, and perform programmatic review as described in Section I-C.2. Based upon this investment strategy, each program then uses a variety of award mechanisms to address the most urgent needs of the research community.

I-C. Proposal Evaluation

The CDMRP uses a two-tiered review process for proposal evaluation as recommended by the National Academy of Science's Institute of Medicine. The two tiers are fundamentally different. The first tier is a scientific peer review of proposals against established criteria for determination of scientific merit. The second tier is a programmatic review of proposals that compares submissions to each other and recommends proposals for funding based on program goals.

I-C.1. Scientific Peer Review

Scientific peer review is conducted by panels organized by scientific discipline, specialty area, or award mechanism. The primary responsibility of the scientific peer review panels is to provide unbiased, expert advice on the scientific and technical merit of proposals, based upon the review criteria published for each award mechanism.

Scientific peer review panels are composed of a chair, scientific reviewers, consumer reviewers, and a nonvoting executive secretary. Selection of individuals as scientific reviewers is predicated upon their expertise as well as their varied levels of experience with scientific peer review. For the breast, prostate, and ovarian cancer research programs, consumer reviewers are cancer survivors and representatives of consumer advocacy organizations. For the neurofibromatosis research program, consumer reviewers are individuals with neurofibromatosis or their family members and representatives of consumer advocacy organizations. Consumer reviewers are nominated by an advocacy organization and are selected on the basis of their leadership skills, commitment to advocacy, and interest in science. Consumers augment the scientific peer review by bringing the patient perspective to the assessment of science and to the relevance of research.

Panel members rate each proposal based on specific evaluation criteria developed for each award mechanism (see Section B of each award mechanism). Two types of ratings are used. First, each of the evaluation criteria, except for the budget, is rated on a scale of 1 (lowest merit) to 10 (highest merit). This criteria scoring ensures that each component is considered in peer review. Second, the overall proposal is given a global priority score using a scale of 1 (highest merit) to 5 (lowest merit). Criteria scores are neither averaged nor mathematically manipulated to determine the global priority score. Instead, reviewers are asked to use the criteria scores as a guide in determining the global priority score. In rare instances, a proposal may be disapproved at scientific peer review if gravely hazardous or unethical procedures are involved, or if the proposal is so seriously flawed as to make its completion implausible.

The peer review summary statement is a product of scientific peer review. Each summary statement includes the investigator's structured technical abstract and lay (nontechnical) abstract (verbatim), the peer review scores, and an evaluation of the project as assessed by the peer reviewers according to the evaluation criteria published in this program announcement. Summary statements are forwarded to the next stage of the review process, programmatic review.

I-C.2. Programmatic Review

The second tier is programmatic review. Programmatic review is accomplished by the IP, which is composed of scientists, clinicians, and consumer advocates. The members of the IP represent many diverse disciplines and specialty areas and are experienced with peer review procedures. Consumer advocates represent national advocacy constituencies and are full voting members of the IP. One of the functions of programmatic review is to select a broad portfolio of grants across all disciplines. Programmatic review is a comparison-based process in which proposals

from multiple research areas compete in a common pool. IP members use the peer review summary statements, which include the proposal abstracts, to review proposals. The Statement of Work may also be reviewed at this level. However, the full proposal is not forwarded to programmatic review.

The IP is committed to funding a broad-based research portfolio. The ratings and evaluations of scientific peer review panels are primary factors in programmatic review; the IP also must consider other criteria to establish this portfolio. The criteria the IP uses to make funding recommendations are:

- Ratings and evaluations of the scientific peer review panels;
- Programmatic relevance;
- Relative innovation; and
- Program portfolio balance with respect to research disciplines or specialty areas.

Scientifically sound proposals that best fulfill the above criteria and most effectively address the unique focus and goals of the program are selected by the IP and recommended to the Commanding General, USAMRMC, for funding.

I-D. Notification

Following completion of the two-tiered evaluation process, every applicant will receive a letter indicating the award status of his or her proposal, along with the peer review summary statement. Letters will be sent as official information becomes available. Thus, not all investigators will be notified at the same time.

I-E. Negotiation of the Award

Award negotiation consists of discussions, reviews, and justifications of several critical issues, including those involving the U.S. Army Medical Research Acquisition Activity (USAMRAA) and Regulatory Compliance and Quality (RCQ). A Contract Specialist from USAMRAA will contact the Administrative Representative who is authorized to negotiate contracts and grants at the applicant's institution. As part of the negotiation process, additional documentation and justifications relating to the proposed Statement of Work and associated budgets may be required.

Please note that the award start date will be determined during the negotiation process.

Concurrent with the USAMRAA discussions, RCQ will review the environmental compliance, safety plan, animal use, and human subjects/anatomical substance use documents to ensure that Army regulations are met. The Certificate of Environmental Compliance and Principal Investigator Safety Program Assurance documents are part of the proposal submission. The Facility Safety Plan (if needed), Research Involving Animals, and Research Involving Human Subjects and/or Anatomical Substances documents will be requested in the applicant's notification letter and will be reviewed by RCQ staff. All documents related to RCQ should be available on the CDMRP web site by April 2002.

I-F. Human Use Requirements Unique to Department of Defense-Funded Research

Important distinctions exist for research funded by the DOD that involves human subjects. In addition to local Institutional Review Board (IRB) approval to conduct research involving human subjects, a second, DOD review and approval is also required. The Human Subjects Research Review Board (HSRRB), administered by the USAMRMC RCQ Office, is responsible for conducting this second level of review. The HSRRB is mandated to comply with specific laws and directives governing all research involving human subjects that is conducted or supported by the DOD. These laws and directives are rigorous and detailed and will require information in addition to that supplied to the local review board. **All research protocols involving human subjects and/or anatomical substances must be approved by <u>both</u> the appropriate local review board <u>and</u> by the HSRRB before awards are made and prior to initiation of the research protocol.**

Two requirements specific to DOD-funded research that the applicant must specifically address, if applicable, in the development of a research proposal for submission to the DOD are outlined below.

- <u>Medical Care for Research-Related Injuries</u>. For all DOD-funded research involving human subjects, medical care for research-related injuries must be provided at no cost to the subject. Many institutions and states provide for this medical care as part of their liability insurance. If not, investigators should plan on budgeting for such costs. The institution business office can assist applicants with budgeting for this requirement. See Appendix F, Part 7 for more details.

- <u>Intent to Benefit</u>. An individual not legally competent to consent (e.g., minors) may not be enrolled in DOD-sponsored research unless the research is intended to benefit each and every subject enrolled in the study. Applicants should be aware that this law makes placebo-controlled clinical trials problematic because of the 'intent to benefit' requirement whenever participation is sought of subjects from whom consent must be obtained by the legally authorized representative. Therefore, applicants should be able to articulate how the research intends to benefit minors or other individuals who are not legally competent to consent and are part of the placebo arm of the study.

More information regarding research involving human subjects can be found in the RCQ Document, "Research Involving Human Subjects and/or Anatomical Substances," which will be available on the CDMRP web site (http://cdmrp.army.mil) by April 2002.

I-G. Annual and Final Reports

All awards will require the timely delivery of several reports during the research effort. These reports are necessary for the CDMRP to monitor progress and evaluate program outcomes. The Principal Investigator (PI) should plan on a reporting requirement consisting of:

- An **annual** report (for each year of research except the final year) that presents a detailed summary of scientific issues and accomplishments; and

- A **final** report (submitted in the last year of the award period) that details the findings and issues for the entire project.

I-H. Publications and Patents

All investigators are strongly encouraged to publish their results in the scientific literature. All publications, abstracts, and presentations must cite the DOD as the source of the research funding. For example, "This research, under Award Number DAMD…, was supported by the Department of Defense Breast Cancer Research Program, which is managed by the U.S. Army Medical Research and Materiel Command." A PI must submit a copy of any manuscript or publication resulting from research funded under the award to the CDMRP.

In accordance with the Bayh-Dole Act (35 USC 200 et seq.[1]), title to inventions and patents resulting from such federally funded research may be held by the grantee or its collaborator, but the U.S. Government shall, at a minimum, retain nonexclusive rights for the use of such inventions. An investigator must follow the instructions in the assistance agreement concerning license agreements and patents.

[1] Title 35, United States Code, Section 200 et seq.

II. Department of Defense Breast Cancer Research Program

II-A. History of the Breast Cancer Research Program

Grass roots advocacy organizations provided the impetus that led to the fiscal year 1993 (FY93) Congressional appropriations to the Department of Defense (DOD) for $210M targeted toward breast cancer research. Since then, due to the ongoing efforts of advocacy groups and increased public awareness on health issues, Congress has continued to appropriate money for breast cancer research managed by the U.S. Army Medical Research and Materiel Command (USAMRMC) through the office of the Congressionally Directed Medical Research Programs (CDMRP). To date, Congress has appropriated more than $1.3 billion to the DOD, through the Breast Cancer Research Program (BCRP), a multidisciplinary effort aimed at the eradication of breast cancer.

A summary program history for FY92-01 appropriations of the BCRP is shown in Tables II-1 and II-2.

Table II-1: History of the DOD's Peer Reviewed BCRP

Program History	FY92[1]-99[2]	FY00	FY01[3]
BCRP-Managed Appropriations for Peer-Reviewed Research	$868.3M	$175.0M	$175.0M
Breast Cancer Stamp[4]	$1.8M	$1.3M	$2.4M
Number of Full Proposals Received	12,009	1,234	1,500
Number of Proposals Funded	2,192	344	371
Percentage of Applications Recommended for Funding	18%	28%	25%
Number of Research Awards[5]	1,331	180	171
Number of Infrastructure Awards[6]	56	6	1
Number of Training/Recruitment Awards	805	158	194
Number of Innovator Awards	-	-	5

[1]Upon establishment of the BCRP in FY93, the CDMRP assumed responsibility for managing the $25M appropriation made in FY92 for breast cancer research that was being administered by the USAMRMC.
[2]Does not include 1,774 FY99 Concept proposals, 98 of which were awarded with FY99 funds and 203 of which were awarded with FY00 funds.
[3]Final numbers for FY01 will be available after September 30, 2002.
[4]Funds received as a result of the Stamp Out Breast Cancer Act (Public Law 105-41, H.R. 1585) are also managed under the BCRP.
[5]Includes Clinical Translational Research (CTR) Awards.
[6]Includes Collaborative-CTR (C-CTR) Awards.

Table II-2: Number of Proposals Received and Number of Awards Made for CTR and C-CTR Awards in FY97-01

Program History	FY97-99[1]	FY00	FY01[2]
Number of CTR and C-CTR Proposals Received			
CTR and C-CTR pre-proposals	437	40	46
CTR and C-CTR full proposals	131	20	16
Number of CTR and C-CTR Awards	21	7	1

[1] The pre-proposal strategy was implemented in FY97.
[2] Final numbers for FY01 will be available after September 30, 2002.

II-B. Overview of the FY02 Breast Cancer Research Program: Two Program Announcements

The CDMRP is requesting proposals on breast cancer research in two separate program announcements. This program announcement (Program Announcement II) is requesting proposals in the following eight award mechanisms: Exploration, Idea, Undergraduate Summer Training Program, Predoctoral Traineeship, Postdoctoral Traineeship, Physician-Scientist Training, Clinical Research Nurse, and Innovator Awards. Program Announcement I (released February 21, 2002) is requesting proposals in five award mechanisms: CTR, Biotechnology Clinical Partnership, C-CTR, Breast Cancer Center of Excellence, and Historically Black Colleges/Minority Institutions (HBCU/MI) Partnership Training Awards. .

The overall goal of the FY02 BCRP is to promote research directed toward eradicating breast cancer. Within this context, the objective of the BCRP is to fund a balanced portfolio of scientifically meritorious research on all aspects of breast cancer. Proposals are sought across all areas of laboratory, clinical, behavioral, and epidemiologic research including all disciplines within the basic, clinical, psychosocial, behavioral, sociocultural, and environmental sciences; nursing; occupational health; alternative therapies; public health and policy; and economics. Additionally, proposals that address the needs of minority, low-income, rural, and other underrepresented and/or medically underserved populations are encouraged.

The USAMRMC is challenging the scientific community to design innovative research that will foster new directions for, address neglected issues in, and bring new investigators into the field of breast cancer research. As in previous years, the central theme of the BCRP is innovation. Scientific ventures that represent underinvestigated avenues of research or novel applications of existing technologies are highly sought. Although the CDMRP wishes to encourage risk-taking research, such projects must nonetheless demonstrate solid scientific judgment and rationale.

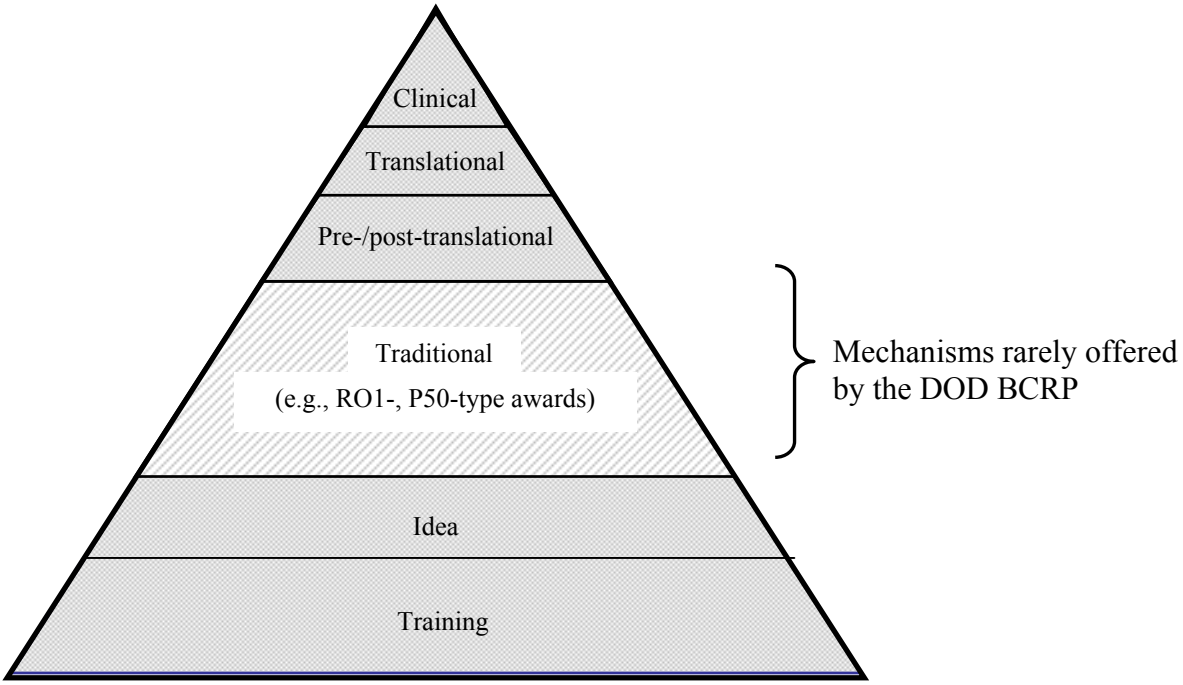
II-C. BCRP Emphasis Areas

The BCRP adapts the types of award mechanisms it offers each year to meet the current needs in breast cancer research and treatment. Mechanisms are developed based upon recommendations of the Integration Panel, an expert panel of scientists, clinicians, and consumer advocates (see Section I-B). Multiple factors are taken into consideration when designing and offering award mechanisms for each fiscal year. In particular, the BCRP factors in funding opportunities that are offered by other agencies. Award mechanisms offered each year complement and fill niches in research that are not offered/emphasized by other agencies. The BCRP funding mechanism philosophy is illustrated by the pyramid depicted in Figure II-1.

- The foundation of the pyramid is the training of investigators in breast cancer research. The FY02 BCRP will offer several training/recruitment awards (see Sections V-IX of this program announcement and FY02 Program Announcement I, released February 21, 2002). New training awards are offered for nurses and physicians who want to pursue clinical research careers (see Sections VIII and IX, respectively); these awards will also directly impact translational and clinical research.

- The second level of the pyramid is ideas; research starts with thousands of ideas, not all of which will lead to fruitful areas of investigation. Idea Awards (Section IV) have been and continue to be a major emphasis of the BCRP; a new Exploration Award (Section III) is also offered to support the initial evaluation of a concept.

Figure II-1. BCRP Funding Philosophy



- The middle of the research pyramid is traditional research projects; these projects are often the major emphasis of a laboratory or research program. Traditional research studies are long-range and typically include studies that can be projected over several years. Traditional research projects have not been emphasized by the DOD BCRP and are requested only in cases when there is a particular need.

- Approaching the pyramid's summit are Translational Awards. The BCRP focuses efforts at the critical juncture between bench and bedside research. CTR Awards support research projects that move bench research into a clinical trial during the life of the award (see Program Announcement I, released February 21, 2002).

- The pinnacle of the pyramid represents the very few research studies that make it to a clinical trial. Biotechnology Clinical Partnership Awards provide an impetus for biotechnology companies and academic institutions to work together to accelerate the delivery of novel breast cancer therapeutics by offering support for Phase 1/2 or Phase 2 clinical trials (see Program Announcement I, released February 21, 2002). The BCRP supports the infrastructure for developing new means to perform clinical trials through C-CTR Awards (see Program Announcement I, released February 21, 2002).

Most awards offered by the BCRP fit into one level of the pyramid. However, in FY02, the BCRP is offering two awards that may either fit a single level or span multiple levels of the pyramid.

- Breast Cancer Center of Excellence Awards may focus on an overarching problem in breast cancer research at any level of this pyramid or may traverse several levels of the pyramid from training and basic research to the clinical use of information (see Program Announcement I, released February 21, 2002).

- Innovator Awards are intended to attract outstanding investigators from a diversity of fields to explore new avenues in breast cancer research (Section X).

II-D. FY02 BCRP Program Announcement Award Opportunities

The programmatic strategy for the BCRP is to fund proposals in three categories: (1) Research Awards, (2) Infrastructure Awards, and (3) Training/Recruitment Awards. In addition, a unique award that does not fit into these categories, the Innovator Award, is included in this program announcement. This Command anticipates that an estimated $136M will be available for the FY02 BCRP to fund competitive, peer reviewed breast cancer research.

The DOD intends that 5.5% of the available monies be used to fund awards at HBCU/MI. (Applicants from HBCU/MI should see Appendix B, part 1 for additional information.) In addition, as a result of the Stamp Out Breast Cancer Act (Public Law 105-41, H.R. 1585), the

DOD BCRP expects to receive approximately $3M in 2002 for breast cancer research. The DOD plans to use all Breast Cancer Stamp monies received prior to November 2002 to fund additional scientifically meritorious Idea Award proposals submitted to the FY02 BCRP.

Additional details of the FY02 budget and the intended allocations for each mechanism are provided in Tables II-3 and II-4.

Table II-3: Estimated Budget for the FY02 BCRP

Congressional Appropriation	**$150.0M**
Less: Congressional/DOD Withholds[1]	($9.6M)
Appropriation Received	$140.4M
Less: Approximate BCRP Management Costs[2]	($7.7M)
Plus: Estimated Stamp Out Breast Cancer Act Proceeds	$3.0M
Amount Available for FY02 Research	**$135.7M**

[1] Withholds include Small Business Innovation Research (SBIR)/USAMRMC. For more information, refer to the Small Business Administration web site (http://www.sba.gov/SBIR).

[2] Any cost savings from management costs will be applied to research funding.

FY02 BCRP budget data are estimated based on prior year's experience and information available for the current year.

Table II-4: Anticipated Investment by Award Category and Mechanism

Research Awards:	**$55.5M**
CTR Awards	$5.1M
Biotechnology Clinical Partnership Awards	$5.1M
Exploration Awards	$6.2M
Idea Awards	$39.1M
Infrastructure Awards:	**$33.9M**
C-CTR Awards	$3.1M
Center Awards	$30.8M
Training/Recruitment Awards:	**$37.0M**
HBCU/MI Partnership Training Awards	$6.2M
Undergraduate Summer Training Program Awards	$2.1M
Predoctoral Traineeship Awards	$5.1M
Postdoctoral Traineeship Awards	$10.3M
Clinical Research Nurse Awards	$5.1M
Physician-Scientist Training Award	$8.2M
Innovator Awards	**$9.3M**
Total	**$135.7M**

Prospective applicants who are familiar with the CDMRP program requirements from previous years are urged to review this program announcement carefully because revisions have been made.

Important note regarding duplicate submissions: Submission of the same research project to the FY02 BCRP under different award mechanisms is **not** allowed, and all such duplicate submissions may be administratively withdrawn. This includes submissions under different award mechanisms by different Principal Investigators. The Government reserves the right to reject any proposal.

Reference Table of Award Mechanisms and Submission Requirements

Award Mechanisms	Experience of Principal Investigator	Key Mechanism Elements	Dollars Available for Individual Awards	Submission Deadline	Instructions for Proposal Preparation
Exploration Awards	All levels of experience	• To support initial evaluation of an imaginative concept for which no preliminary data is available • 90% emphasis on innovation	A maximum award of $150,000 for direct costs for a period of up to 18 months	June 13, 2002 11:59 p.m. (applicant's local time)	Section III
Idea Awards	All levels of experience	• No preliminary data required • Reward innovative ideas and technology • 50% emphasis on innovation	A maximum award of $300,000 in direct costs for a period of up to 3 years; population-based studies may request a maximum award limit of $625,000 in direct costs for a period of up to 5 years	June 11, 2002 11:59 p.m. (applicant's local time)	Section IV
Undergraduate Summer Training Program Awards	All levels of experience	• Supports 4-8 students for summer internships • To encourage undergraduate students to pursue careers in breast cancer research	An award of $4,000/student per summer and up to $25,000/year for administrative costs for up to 3 years	June 12, 2002 11:59 p.m. (applicant's local time)	Section V
Predoctoral Traineeship Awards	Predoctoral students	• Prepare new scientists for careers in breast cancer research	An average of $30,000/year for direct and indirect costs for up to 3 years	June 12, 2002 11:59 p.m. (applicant's local time)	Section VI
Postdoctoral Traineeship Awards	Recent doctoral graduates with less than 5 years of postdoctoral research experience	• Prepare new scientists and clinicians for careers in breast cancer research	An average of $57,000/year for direct and indirect costs for up to 3 years	June 12, 2002 11:59 p.m. (applicant's local time)	Section VII
Clinical Research Nurse Awards	Nurses with a bachelor, masters, or doctoral level nursing degree	• Prepare nurses for clinical breast cancer research careers • Interdisciplinary, mentored training environment • Didactic and experiential training	Up to $100,000/year inclusive of direct and indirect costs for a period of 2 years; a maximum of $75,000/year for salary and $25,000/year for other expenses	June 12, 2002 11:59 p.m. (applicant's local time)	Section VIII

(Table continued on next page)

Reference Table of Award Mechanisms and Submission Requirements (cont'd)

Award Mechanisms	Experience of Principal Investigator	Key Mechanism Elements	Dollars Available for Individual Awards	Submission Deadline	Instructions for Proposal Preparation
Physician-Scientist Training Awards	Physicians in the last year of oncology graduate medical education or within the first 3 years of a faculty appointment	• Prepare physicians for careers in clinical breast cancer research through a mentored training experience • To relieve applicants from academic or clinical responsibilities • Requires 5-year commitment to clinical breast cancer research • Provides salary support and medical school education loan debt reduction • Requires separate source of research support	A maximum of $700,000 inclusive of direct, indirect, and tuition debt reduction costs for a period of 5 years; including up to 60% of PI's salary and up to 50% of key support person's salary for 3 years, plus up to $40,000/year for qualifying medical school education loans for 5 years	June 12, 2002 11:59 p.m. (applicant's local time)	Section IX
Innovator Awards	Scholars from any field with outstanding record of creative accomplishments	• Encourage creative and visionary breast cancer research • Primary award basis is individual's talent and potential • Traditional research proposal not required	A maximum award of $3M for direct and indirect costs for a period of up to 4 years	Required Letter of Intent: May 30, 2002 11:59 p.m. (applicant's local time) Application: June 13, 2002 11:59 p.m. (applicant's local time)	Section X

III. Exploration Awards

III-A. Exploration Awards

The intent of Exploration Awards is to fund an initial concept or theory (with no preliminary data) that could give rise to a testable hypothesis. These awards are to encourage the exploration of untested, innovative questions in breast cancer. A goal of the Exploration Awards is to promote creative thinking that will yield imaginative concepts, ideas, and approaches at the dynamic interfaces of different areas of science, including those not traditionally or extensively involved in cancer research. These awards should provide investigators who have potentially insightful ideas from disciplines and fields outside breast cancer with an entrée to the breast cancer research field.

Exploration Award proposals are not intended to support a logical progression of an already established research project, but should represent a new paradigm in the study of breast cancer, challenge existing paradigms, or look at an existing problem from a new, untested perspective. The proposed studies should have the potential to reveal new avenues of investigation. These awards provide investigators with the opportunity to pursue serendipitous observations, and it is anticipated that research completed through an Exploration Award may provide sufficient preliminary data to enable the investigator to prepare a hypothesis-based proposal for further research. Because these awards are designed for preliminary investigations, projects involving human subjects or specimens will not be supported through this mechanism unless they are exempt under 32 CFR 219.101(b)(4).[1] Studies that do not qualify for exempt status during review at any level will be administratively withdrawn and will not be funded.

Innovation will be the major review criterion for this award. The Breast Cancer Research Program (BCRP) anticipates that the submission of truly innovative proposals will result in high risk and high impact research. Exploration Award proposals should represent the start of something new, creating or introducing a unique or unusual approach to the study of breast cancer. As a guideline to applicants and reviewers, proposals may be innovative in a variety of ways, including the following:

- Study concept – Investigation of a novel idea and/or unique research question.
- Research method or technology – Use of novel research methods or new technologies to address a research question.

[1] Title 32, Code of Federal Regulations, Part 219, Section 101(b)(4).

Research involving collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, is considered to be exempt under 32 CFR 219.101(b)(4). For additional information, refer to the document Research Involving Human Subjects and/or Anatomical Substances that will be available on the CDMRP web site at http://cdmrp.army.mil by April 2002.

- Development of clinical interventions – Novel methods or technologies for preventing, detecting, diagnosing, or treating breast cancer (can include animal models or retrospective studies which are exempt under 32 CFR 219.101(b)(4)).

- Adaptations of existing methods or technologies – Application or adaptation of existing methods or technologies for research or clinical purposes that are fundamentally different from the purposes originally intended and/or for use under novel research or clinical purposes.

This list is not all-inclusive, but is intended to serve as a scaffold on which to frame the innovative features of the proposal. It is the responsibility of the investigator to clearly articulate how the proposed research is innovative.

Innovative ideas are also a hallmark of the Idea Awards (Section IV) offered by the BCRP since fiscal year 1993. However, there are several significant differences between Idea Awards and Exploration Awards as outlined in Table III-1 below. Idea Awards do not require preliminary data; however, Idea Award proposals have frequently included a minimum amount of pilot data. The concept for an Exploration Award should be untested, thus preliminary data should not be available. Idea Awards must have a hypothesis based on a sound scientific rationale supported through a critical review and analysis of the literature, logical reasoning, and/or the use of preliminary data. An Exploration Award may (but does not have to) precede the articulation of a hypothesis. Some gaps in supporting rationale for an Exploration Award may exist due to a lack of available information. Results of studies conducted through an Exploration Award may provide the scientific rationale upon which a new hypothesis can be based. Another distinction is that the ***maximum*** award amount and duration for the Exploration Award is half that offered for the Idea Award (however, please note that Idea Awards can be submitted for any period up to 3 years, i.e., 1, 1.5, 2, or 2.5 years).

Table III-1: Differences between Exploration Award and Idea Award Proposals

Mechanism	Statement of Hypothesis	Preliminary or Pilot Data	Use of Human Subjects or Human Anatomical Substances	Emphasis on Innovation	Maximum Award Amount and Duration
Exploration	Proposed work may precede formulation of hypothesis	Do not exist	Not allowed*	90%	$150,000 in direct costs for up to 18 months
Idea	Required	Not required (can be included if available)	Allowed	50%	$300,000 in direct costs for up to 3 years

* Unless exempt under 32 CFR 219.101(b)(4). Studies exempt under 32 CFR 219.101(b)(4) include research involving collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified.

Approximately $6M will be available for Exploration Awards. Funding for Exploration Awards can be requested for a maximum of $150,000 in direct costs for a period of up to 18 months, plus indirect costs as appropriate. Direct costs can cover salary, expenses (including research supplies), equipment, and travel to scientific meetings.

For complete proposal requirements, please refer to Section III-E. Additional guidance for proposal preparation may be gained by reviewing the peer and programmatic review criteria listed in Sections III-B and III-C.

Submission of the same research project to the FY02 BCRP under different award mechanisms will not be allowed, and all such duplicate submissions may be administratively withdrawn. This includes submissions under different award mechanisms from different Principal Investigators (PIs). The Government reserves the right to reject any proposal.

III-B. Scientific Peer Review Evaluation Criteria for Exploration Award Proposals

Scientific peer review will focus on the intent of the Exploration Award mechanism to encourage the exploration of untested, innovative questions in breast cancer. Although criteria scores are neither averaged nor mathematically manipulated to determine the global priority score (see Section I-C.1), peer reviewers will be given guidance that the majority of the global priority score (90%) should reflect their evaluation of the innovation of the proposal.

Exploration Award proposals will be evaluated according to the criteria listed below:

- **Innovation:** Does the proposal address an untested problem in breast cancer research, or look at an existing problem from a new and untested perspective? Is the proposed research innovative in study concept or question, research methods or technologies, development of clinical interventions, adaptations of existing methods or technologies, or in other ways?

- **Disease Relevance:** Does this study address a critical problem in breast cancer research? What will be the effect of these studies on the concepts or methods that drive this field? Does the proposal make a convincing case for the relevance of the research to breast cancer? To what extent will the project, if successful, make an original and important contribution to the goal of eradicating breast cancer and/or advancing research in the field?

- **Principal Investigator:** Is the PI appropriately trained and well suited to carry out this work? If the proposed work is not in an area in which the PI has experience, is there evidence that advice and input will be obtained from other appropriate sources (e.g., collaborators and colleagues, or the completion of a training course)? Is the proposed work appropriate to the experience level of the PI and other researchers (if any)? Has the PI demonstrated an adequately developed rationale well-integrated with the aims of the project?

- **Budget:** Is the budget appropriate for the research proposed?

III-C. Programmatic Review Evaluation Criteria for Exploration Award Proposals

Funding recommendations at this second tier of review are based on a comparative process. Applicants are reminded of the importance of programmatic relevance and the importance of meeting the intent of the Exploration Award mechanism. Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.2.

III-D. Letter of Intent

All applicants considering submission of a proposal in response to this program announcement are requested to submit an electronic Letter of Intent no later than May 30, 2002. This form can be found on the Congressionally Directed Medical Research Programs (CDMRP) web site at http://cdmrp.army.mil/funding/02bcrp2.htm.

III-E. Proposal Preparation

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for Exploration Awards. Please note that the body of the proposal is limited to **3 pages**, inclusive of any figures, tables, graphs, and photographs. **Proposals exceeding specified page limits may be administratively withdrawn by the Government prior to peer review.**

Ensure that one electronic Portable Document Format (PDF) version of your proposal, which will serve as the official proposal submission, is uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet no later than **11:59 p.m. (applicant's local time) June 13, 2002.** Applicants are required to submit the Proposal Information prior to upload/submission of the proposal. Applicants are encouraged to begin this part of the submission process early and submit their Proposal Information at least 2 weeks prior to the submission deadline. **Applicants unfamiliar with the preparation and submission of PDF files are encouraged to acquire the software and learn the process well before the submission deadline.**

1. Who May Apply – See Appendix B, part 1.

2. Proposal Acceptance Criteria – See Appendix B, part 2.

3. Resubmissions and Duplicate Submissions – See Appendix B, part 3.

4. Proposal Information – See Appendix B, part 4 and Appendix C.

5. Title/Referral Page – See Appendix B, part 5.

6. Table of Contents – See Appendix B, part 6.
   Use the table of contents at the end of this section in your proposal submission. This table of contents should be used as a guide for assembling all required components of the proposal. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the proposal that includes the PI's name (last name, first name, middle initial) and proposal log number (this number will be automatically provided when a draft of the Proposal Information is saved; see Appendix C).

7. Checklist for Proposal Submission – See Appendix B, part 7.

8. Proposal Abstracts – See Appendix B, part 8 and Appendix D.

9. Statement of Work – See Appendix B, part 9 and Appendix D.

10. Proposal Relevance Statement – See Appendix B, part 10.
    In addition to the instructions found in Appendix B, part 10, Exploration Award applicants should state explicitly (within the 1-page limit) how the proposed work is innovative and relevant to breast cancer biology, etiology, prevention, detection, diagnosis, and/or therapy. Articulate how the combination of innovation and relevance in the proposal will impact and further programmatic goals.

11. Proposal Body – See Appendix B, part 11.
    The body of Exploration Award proposals is limited to **3 pages,** inclusive of figures, tables, graphs, and photographs, if used.

    For Exploration Award proposals, it is the responsibility of the investigator to clearly articulate how the proposed research is innovative. Investigators must explain the rationale for the concept to be explored.

    Describe the proposed project using the general outline provided below:

    a. Background: Provide a brief statement of the ideas and reasoning behind the proposed work. Describe previous experience most pertinent to this proposal. Cite relevant literature references.

    b. Concept: State the concept to be explored and the possible outcomes.

    c. Objectives: State concisely the specific aims and a plan for how the project will be executed.

    d. Innovation: State concisely how the proposed research explores an innovative concept or uses innovative methods to advance the understanding of breast cancer biology or etiology or the prevention, detection, diagnosis, and/or treatment of breast cancer.

12. Abbreviations – See Appendix B, part 12.

13. References – See Appendix B, part 13.

14. Biographical Sketches – See Appendix B, part 14 and Appendix E.

15. Existing/Pending Support – See Appendix B, part 15.

16. Facilities/Equipment Description – See Appendix B, part 16.

17. Administrative Documentation – See Appendix B, part 17.
    Administrative documentation **will not** be accepted separately from the electronic submission. All documents or letters must be signed and then scanned into the proposal prior to submission.

    Proposals lacking required administrative documentation may be considered noncompliant and thus may not be forwarded for review (see Appendix B, part 22).

18. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.
    Funding for Exploration Awards can be requested for a maximum of $150,000 in direct costs for a period of up to 18 months, plus indirect costs as appropriate. Direct costs can cover salary, expenses including research supplies, equipment, and travel to scientific meetings. The amount allotted for travel is $1,800 to attend scientific/technical meetings. In addition, funding should be requested for a one-time, 3½-day meeting to disseminate the results of Department of Defense-sponsored research. Applicants are asked to budget for this meeting in year 2 of the Detailed Cost Estimate Form.

19. Instruments – See Appendix B, part 19.

20. Publications and/or Patent Abstracts – See Appendix B, part 20.

21. Proposal Submission – See Appendix B, part 21.

22. Submission Deadline – See Appendix B, part 22.
    Please note that one electronic PDF version of your proposal must be uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet no later than **11:59 p.m. (applicant's local time) June 13, 2002. Submission of a proposal after the deadline may be grounds for proposal rejection.**

23. Regulatory Compliance and Quality Requirements – See Appendix B, part 23.
    Please note that only projects considered exempt under 32 CFR 219.101(b)(4) may be submitted under the Exploration Award mechanism. Studies exempt under 32 CFR 219.101(b)(4) include research involving collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified.

    The one-page Certificate of Environmental Compliance and one-page Principal Investigator Safety Program Assurance documents are to be submitted with the proposal. Additional documents related to Regulatory Compliance and Quality issues should be available on the CDMRP web site by April 2002. See Appendix B, part 23 for more details.

Principal Investigator: _____
Last Name *First Name* *MI*

Proposal Title: _____

_____

Exploration Award Proposal
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References (no page limit) ..... ___
Biographical Sketches (3-page limit each)
  PI (Exploration Applicant) ..... ___
  Key Personnel (including collaborating investigators and support staff) ..... ___
Existing/Pending Support (no page limit) ..... ___
Facilities/Equipment Description (no page limit) ..... ___
Administrative Documentation (no page limit)
  List of all items included in this section ..... ___
  Letters of support from collaborating individuals and/or institutions ..... ___
Detailed Cost Estimate (no page limit) ..... ___
Instruments (no page limit) ..... ___
Publications and/or Patent Abstracts (5-document limit) ..... ___
Certificate of Environmental Compliance ..... ___
Principal Investigator Safety Program Assurance ..... ___

IV. Idea Awards

IV-A. Idea Awards

The intent of Idea Awards is to encourage innovative approaches to breast cancer research. Consistent with this, innovation will receive 50% emphasis in the first tier review of Idea Award proposals. These proposals may represent a new paradigm in the study of breast cancer, challenge existing paradigms, or look at an existing problem from a new perspective. The proposed studies may be untested, but should have a high probability of revealing new avenues of investigation. Although this research is inherently risky in nature, the research plan must demonstrate solid scientific judgment and rationale.

Idea Awards are not intended to continue avenues of research already established. The incremental advancement of a hypothesis, the exploration of a hypothesis in a different cell line, or the use of a published series of in vitro assays to further characterize a model system are examples of aims appropriate for other funding mechanisms. The Breast Cancer Research Program (BCRP) anticipates that the submission of truly innovative proposals will result in high risk and high impact research.

Both Idea Award and Exploration Award (Section III) proposals are qualitatively different from traditional research proposals as outlined in Table IV-1 below. Although Idea Award proposals do not require preliminary or pilot data, they should be based on a sound scientific rationale established through a critical review and analysis of the literature and/or logical reasoning. The research strategy will be evaluated based on appropriateness of the design to test the hypothesis, whether or not the hypothesis is ultimately proven or disproven. Exploration Awards support research at an even earlier stage than Idea Awards and provide funds to initially evaluate new, imaginative concepts for which no preliminary data is available.

Table IV-1: Differences between Traditional Research Proposals and Idea or Exploration Research Proposals

Type of Proposal	Preliminary or Pilot Data	Research Approach	Emphasis of Review
Traditional Research Proposal	Required	Continues established avenues of research	Probability of success
Idea Award Research Proposal	Not required (can be included if available)	Challenges existing paradigms; novel, high risk, potential for high gain	Innovation (50%)
Exploration Award Research Proposal	Do not exist	Initial evaluation of a new concept	Innovation (90%)

Innovation will receive 50% emphasis in the evaluation of Idea Awards. Idea Award proposals should create or introduce a unique or unusual approach to the study of breast cancer. As a guideline to applicants and reviewers, proposals may be innovative in a variety of ways, including the following:

- Study concept – Investigation of a novel idea and/or unique research question.
- Research method or technology – Use of novel research methods or new technologies to address a research question.
- Clinical interventions – Use of a novel method or technology for preventing, detecting, diagnosing, or treating breast cancer.
- Adaptations of existing methods or technologies – Application or adaptation of existing methods or technologies for research or clinical purposes that are fundamentally different from the purposes originally intended and/or for use under novel research or clinical purposes.

This list is not all-inclusive, but is intended to serve as a scaffold on which to frame the innovative features of the proposal. It is the responsibility of the investigator to clearly articulate how the proposed research is innovative.

Approximately $39M will be available for Idea Awards. Funding for Idea Awards can be requested for a maximum of $300,000 in direct costs for a period of up to 3 years, plus indirect costs as appropriate. With compelling justification, population-based studies, especially those that address cancer control or social/behavioral aspects of cancer care, may request a maximum of $625,000 in direct costs for a period of up to 5 years, plus indirect costs as appropriate. (A population-based study requires extra time and resources due to the participation of human subjects.) Direct costs can cover salary, expenses (including research supplies), equipment, and travel to scientific meetings.

For complete proposal requirements, please refer to Section IV-E. Additional guidance for proposal preparation may be gained by reviewing the peer and programmatic review criteria listed in Sections IV-B and IV-C.

Submission of the same research project to the Fiscal Year 2002 BCRP under different award mechanisms will not be allowed, and all such duplicate submissions may be administratively withdrawn. This includes submissions under different award mechanisms from different Principal Investigators (PIs). The Government reserves the right to reject any proposal.

IV-B. Scientific Peer Review Evaluation Criteria for Idea Award Proposals

Scientific peer review will focus on the intent of the Idea Award mechanism to encourage innovative approaches to breast cancer research. Although criteria scores are neither averaged nor mathematically manipulated to determine the global priority score (see Section I-C.1), reviewers will be given guidance that approximately half of the global priority score should reflect their evaluation of the innovation of the proposal.

Idea Award proposals will be evaluated according to the criteria listed below:

- **Innovation:** Is the proposed research innovative in study concept or question, research methods or technologies, clinical interventions, adaptations of existing methods or technologies, or in other ways? Does the project propose new paradigms, challenge existing paradigms, or address underexplored or unexplored areas? Is the project one for which innovation is not necessary?

- **Disease Relevance:** Does this study address a critical problem in breast cancer research? What will be the effect of these studies on the concepts or methods that drive this field? Does the proposal make a convincing case for the relevance of the research to breast cancer? To what extent will the project, if successful, make an original and important contribution to the goal of eradicating breast cancer and/or advancing research in the field?

- **Research Strategy:** Are the conceptual framework, hypotheses, design, methods, and analyses adequately developed and well integrated to the aims of the project? Preliminary data are **not** required but may be included. Has a sound scientific rationale been presented through a critical review and analysis of the literature, logical reasoning, and/or the use of preliminary data? If the research plan requires statistical analysis, is there a clear statistical plan with power analysis included in the proposal? Does the applicant acknowledge potential problem areas and consider alternative methods/tactics?

- **Principal Investigator:** Is the PI appropriately trained and well suited to carry out this work? Is the proposed work appropriate to the experience level of the PI and other researchers (if any)? Is there appropriate representation from all the expertise areas needed to conduct the study successfully?

- **Environment:** Is there evidence that the scientific environment is an appropriate setting for the proposed research? Are the research requirements adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed? Is there evidence of institutional support?

- **Budget:** Is the budget appropriate for the research proposed?

IV-C. Programmatic Review Evaluation Criteria for Idea Award Proposals

Funding recommendations at this second tier of review are based on a comparative process. Applicants are reminded of the importance of programmatic relevance and the importance of meeting the intent of the Idea Award mechanism. Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.2.

IV-D. Letter of Intent

All applicants considering submission of a proposal in response to this program announcement are requested to submit an electronic Letter of Intent no later than May 30, 2002. This form can be found on the Congressionally Directed Medical Research Programs (CDMRP) web site at http://cdmrp.army.mil/funding/02bcrp2.htm.

IV-E. Proposal Preparation

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for Idea Awards. Please note that the body of the proposal is limited to **6 pages**, inclusive of any figures, tables, graphs, and photographs. **Proposals exceeding specified page limits may be administratively withdrawn by the Government prior to peer review.**

Ensure that one electronic Portable Document Format (PDF) version of your proposal, which will serve as the official proposal submission, is uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet by **11:59 p.m. (applicant's local time) June 11, 2002.** Applicants are required to submit the Proposal Information prior to upload/submission of the proposal. Applicants are encouraged to begin this part of the submission process early and submit their Proposal Information at least 2 weeks prior to the submission deadline. **Applicants unfamiliar with the preparation and submission of PDF files are encouraged to acquire the software and learn the process well before the submission deadline.**

1. Who May Apply – See Appendix B, part 1.

2. Proposal Acceptance Criteria – See Appendix B, part 2.

3. Resubmissions and Duplicate Submissions – See Appendix B, part 3.

4. Proposal Information – See Appendix B, part 4 and Appendix C.

5. Title/Referral Page – See Appendix B, part 5.

6. Table of Contents – See Appendix B, part 6.
   Use the table of contents at the end of this section in your proposal submission. This table of contents should be used as a guide for assembling all required components of the proposal. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the proposal that includes the PI's name (last name, first name, middle initial) and proposal log number (this number will be automatically provided when a draft of the Proposal Information is saved; see Appendix C).

7. Checklist for Proposal Submission – See Appendix B, part 7.

8. Proposal Abstracts – See Appendix B, part 8 and Appendix D.

9. Statement of Work – See Appendix B, part 9 and Appendix D.

10. Proposal Relevance Statement – See Appendix B, part 10.
    In addition to the instructions found in Appendix B, part 10, Idea Award applicants should state explicitly (within the 1-page limit) how the proposed work is innovative and relevant to breast cancer biology, etiology, prevention, detection, diagnosis, and/or therapy. Articulate how the combination of innovation and relevance in the proposal will impact and further programmatic goals.

11. Proposal Body – See Appendix B, part 11.
    The body of Idea Award proposals is limited to **6 pages,** inclusive of figures, tables, graphs, and photographs, if used.

    For Idea Award proposals, it is the responsibility of the investigator to clearly articulate how the proposed research is innovative. The inclusion of preliminary data is **not** required; however, investigators must demonstrate a sound scientific rationale established through a critical review and analysis of the literature and/or logical reasoning.

    Describe the proposed project using the general outline provided below:

    a. Background: Provide a brief statement of the ideas and reasoning behind the proposed work. Describe previous experience most pertinent to this proposal. Cite relevant literature references.

    b. Hypothesis/Rationale/Purpose: State the hypothesis to be tested and the expected results.

    c. Objectives: State concisely the specific aims and the research strategy of the study.

    d. Methods: Give details about the experimental design and methodology. If the methodology is new or unusual, describe it in sufficient detail for evaluation.

    e. Innovation: State concisely how the proposed research uses innovative hypotheses or

methods to advance the prevention, detection, diagnosis, and/or treatment of breast cancer.

12. Abbreviations – See Appendix B, part 12.

13. References – See Appendix B, part 13.

14. Biographical Sketches – See Appendix B, part 14 and Appendix E.

15. Existing/Pending Support – See Appendix B, part 15.

16. Facilities/Equipment Description – See Appendix B, part 16.

17. Administrative Documentation – See Appendix B, part 17.
    Administrative documentation **will not** be accepted separately from the electronic submission. All documents or letters must be signed and then scanned into the proposal prior to submission.

    Proposals lacking required administrative documentation may be considered noncompliant and thus may not be forwarded for review (see Appendix B, part 22).

18. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.
    Funding for Idea Awards can be requested for a maximum of $300,000 in direct costs for a period of up to 3 years, plus indirect costs as appropriate. With compelling justification, population-based studies, especially those that address cancer control or social/behavioral aspects of cancer care, may request a maximum of $625,000 in direct costs for a period of up to 5 years, plus indirect costs as appropriate. Direct costs can cover salary, expenses including research supplies, equipment, and travel to scientific meetings. The amount allotted for travel is $1,800 per year to attend scientific/technical meetings. In addition, funding should be requested for a one-time, 3½-day meeting to disseminate the results of Department of Defense (DOD)-sponsored research. Applicants are asked to budget for this meeting in year 2 of the Detailed Cost Estimate Form.

    For all DOD-funded research involving human subjects, medical care for research-related injuries must be provided at no cost to the subject. Many institutions and states provide for this medical care as part of their liability insurance. If not, investigators should plan on budgeting for such costs. The institution business office can assist applicants with budgeting for this requirement. See Appendix F for more details.

19. Instruments – See Appendix B, part 19.

20. Publications and/or Patent Abstracts – See Appendix B, part 20.

21. Proposal Submission – See Appendix B, part 21.

22. Submission Deadline – See Appendix B, part 22.
    Please note that one electronic PDF version of your proposal must be uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet by **11:59 p.m. (applicant's local time) June 11, 2002. Submission of a proposal after the deadline may be grounds for proposal rejection.**

23. Regulatory Compliance and Quality Requirements – See Appendix B, part 23.
    The one-page Certificate of Environmental Compliance and one-page Principal Investigator Safety Program Assurance documents are to be submitted with the proposal. Additional documents related to Regulatory Compliance and Quality issues should be available on the CDMRP web site by April 2002. See Appendix B, part 23 for more details.

Principal Investigator: _____
Last Name *First Name* *MI*

Proposal Title: _____

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Abbreviations (1-page limit) ..... ___
References (no page limit) ..... ___
Biographical Sketches (3-page limit each)
  PI (Idea Applicant) ..... ___
  Key Personnel (including collaborating investigators and support staff) ..... ___
Existing/Pending Support (no page limit) ..... ___
Facilities/Equipment Description (no page limit) ..... ___
Administrative Documentation (no page limit)
  List of all items included in this section ..... ___
  Letters of support from collaborating individuals and/or institutions ..... ___
Detailed Cost Estimate (no page limit) ..... ___
Instruments (no page limit) ..... ___
Publications and/or Patent Abstracts (5-document limit) ..... ___
Certificate of Environmental Compliance ..... ___
Principal Investigator Safety Program Assurance ..... ___

V. Undergraduate Summer Training Program Awards

V-A. Undergraduate Summer Training Program Awards

The intent of the Undergraduate Summer Training Program Awards (Undergraduate Awards) is to establish summer breast cancer training programs that will provide meaningful research experiences for undergraduate students. A goal of the Undergraduate Award is to attract talented students to careers that focus on breast cancer research. It is anticipated that these awards will provide educational and training opportunities for undergraduate students at an important career decision-making point.

Undergraduate Award proposals must have a minimum of four and a maximum of eight undergraduate students per year. Students should spend 8-12 weeks of the summer participating in the program. The undergraduate students in this program can be named or designated "to be named" (TBN) at the time of proposal submission.

One or more mentors may be involved in the training program. When a proposal includes multiple staff members, a single individual should be clearly designated as the Program Director, i.e., the Principal Investigator (PI) for the proposal.

Applications are solicited from all eligible institutions. Eligible institutions include for-profit, non-profit, public, or private organizations. Examples include universities, colleges, hospitals, laboratories, companies, and agencies of local, state, and federal governments. The Congressionally Directed Medical Research Programs (CDMRP) encourages proposals from Historically Black Colleges and Universities/Minority Institutions for Undergraduate Awards (see Appendix B, part 1).

Undergraduate Award proposals should address the following key aspects for the proposed breast cancer undergraduate training program: (1) the program vision and goals, particularly as they relate to breast cancer; (2) the program faculty/staff; (3) the training program; and (4) the trainee recruitment plans. In the development of recruitment plans, methods to encourage the participation of women and minority students should be considered. For complete proposal requirements, please refer to Section V-E. Additional guidance for proposal preparation may be gained by reviewing the peer and programmatic review criteria listed in Sections V-B and V-C.

Approximately $2M will be available for Undergraduate Awards. Funding for these awards can be requested for a $4,000 stipend per student per summer and up to $25,000 per year for administrative costs over a 3-year performance period for a maximum total of $171,000 in direct costs. Direct costs can cover tuition, student stipends, faculty salary, and expenses including research supplies.

Submission of the same research project to the Fiscal Year 2002 BCRP under different award mechanisms will not be allowed, and all such duplicate submissions may be administratively withdrawn. This includes submissions under different award mechanisms from different PIs. The Government reserves the right to reject any proposal.

V-B. Scientific Peer Review Evaluation Criteria for Undergraduate Summer Training Award Proposals

Undergraduate Award proposals will be evaluated according to the criteria listed below:

- **Training Program:** Does the training program offer a structured, focused experience in breast cancer research? Does the program ensure direct, structured interaction between mentor and student? Have plans been developed to provide students with a stimulating, problem-solving research experience? Does the program provide mechanisms for students to summarize and present their work? Does the training program provide opportunities for students to interact with other program mentors outside the laboratory in which they are working? Has a plan been developed to track the students' future careers and the effectiveness of the program for initiating careers in breast cancer research?

- **Program Director and Training Staff:** Does the Program Director (the PI) have the background, research qualifications, and ability to lead and successfully manage an undergraduate breast cancer training program? What are the research interests and records of past experience in training and mentoring undergraduates of the participating mentors? Is there a sufficient number of mentors with research resources participating in the program to ensure adequate mentoring and supervision for the number of student trainees?

- **Trainees:** What methods are used to recruit trainees? Are the selection criteria for admitting students into the program appropriate? Are the recruitment methods likely to attract students with a high likelihood of pursuing a career in breast cancer research? What is the overall quality of present and former students, if applicable? Have former undergraduate trainees (if any) gone on to pursue careers in breast cancer research? Is the size, i.e., number of trainees, appropriate for the available faculty/resources?

- **Relevance:** Will the training of the students be relevant to breast cancer?

- **Institutional Environment:** Is there evidence of a strong institutional commitment to research training in breast cancer? Does the institution have other undergraduate research opportunities? Does the institution provide an intellectually stimulating environment and facilitate interaction among mentors and trainees? Does the institution provide adequate laboratory facilities, equipment, and other relevant resources to support these training activities?

- **Budget:** Is the budget appropriate for the proposal?

V-C. Programmatic Review Evaluation Criteria for Undergraduate Summer Training Program Awards

Funding recommendations at this second tier of review are based on a comparative process. Applicants are reminded of the importance of programmatic relevance and the importance of meeting the intent of the Undergraduate Award mechanism. Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.

V-D. Letter of Intent

All applicants considering submission of a proposal in response to this program announcement are requested to submit an electronic Letter of Intent no later than May 30, 2002. This form can be found on the CDMRP web site at http://cdmrp.army.mil/funding/02bcrp2.htm.

V-E. Proposal Preparation

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for Undergraduate Awards. Please note that the body of the proposal is limited to **6 pages,** inclusive of any figures, tables, graphs, and photographs. **Proposals exceeding specified page limits may be administratively withdrawn by the Government prior to peer review.**

Ensure that one electronic Portable Document Format (PDF) version of your proposal, which will serve as the official proposal submission, is uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet no later than **11:59 p.m. (applicant's local time) June 12, 2002.** Applicants are required to submit the Proposal Information prior to upload/submission of the proposal. Applicants are encouraged to begin this part of the submission process early and submit their Proposal Information at least 2 weeks prior to the submission deadline. **Applicants unfamiliar with the preparation and submission of PDF files are encouraged to acquire the software and learn the process well before the submission deadline.**

1. Who May Apply – See Appendix B, part 1.

2. Proposal Acceptance Criteria – See Appendix B, part 2.

3. Resubmissions and Duplicate Submissions – See Appendix B, part 3.

4. Proposal Information – See Appendix B, part 4 and Appendix C.

5. Title/Referral Page – See Appendix B, part 5.

6. Table of Contents – See Appendix B, part 6.
   Use the table of contents at the end of this section in your proposal submission. This table of contents should be used as a guide for assembling all required components of the proposal. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the proposal that includes the PI's name (last name, first name, middle initial) and proposal log number (this number will be automatically provided when a draft of the electronic Proposal Information is saved; see Appendix C).

7. Checklist for Proposal Submission – See Appendix B, part 7.

8. Proposal Abstracts – See Appendix B, part 8 and Appendix D.

9. Statement of Work – See Appendix B, part 9 and Appendix D.
   The first summer training program should be planned for summer 2003.

10. Proposal Relevance Statement – See Appendix B, part 10.
    In addition to the instructions found in Appendix B, part 10, Undergraduate Award proposals should describe (within the 1-page limit) how the training program will be designed to offer a structured, well-rounded, focused experience in breast cancer research. Include how the training program will foster the likelihood of its trainees pursuing a career in breast cancer research.

11. Proposal Body – See Appendix B, part 11.
    The body of Undergraduate Award proposals is limited to **6 pages,** inclusive of figures, tables, graphs, and photographs, if used.

    Undergraduate Award proposals should address the following key aspects of the proposed training program: (1) the program vision and goals, particularly as they relate to breast cancer; (2) the program faculty/staff; (3) the training program; and (4) the trainee recruitment plans. As part of the discussion of each of these key aspects, the body of the proposal should address the breast cancer emphasis of the program; the qualifications of the Program Director and any additional participating mentors; the training environment and facilities; the proposed research opportunities available for trainees; the recruitment of students into the program; the selection criteria for students; the method of assigning students to a mentor; and the plan for tracking students after participation in the program to determine how many go on to pursue careers involving breast cancer research. In the development of recruitment plans, methods to encourage the participation of female and minority students should be considered. An outline of any course or seminar series that might be available as part of the training program could be included. Additional information on the participating mentors/trainees and institutional support is to be described in the Biographical Sketches and Administration Documentation sections (see items 14 and 17, respectively, on page V-5).

12. Abbreviations – See Appendix B, part 12.

13. References – See Appendix B, part 13.

14. Biographical Sketches – See Appendix B, part 14 and Appendix E.

    a. Mentor Biographical Sketches: Biographical sketches should include a section describing the Program Director's (the PI's) and training staff members' experience in the field of breast cancer research and previous experience training and mentoring students, particularly undergraduates. A list of significant publications in breast cancer research should be incorporated into the biographical sketches.

    b. Trainee Biographical Sketches: A biographical sketch of no more than 3 pages must be included in this section for **named** trainees. The Biographical Sketch Form in Appendix E should be used, but emphasis should be placed on the trainee's interests and career goals, relevant coursework and extracurricular activities, and any past experience in scientific research. When TBN trainees are ultimately selected, the CDMRP must be notified, and the name and biographical sketch of each trainee must be provided.

15. Existing/Pending Support – See Appendix B, part 15.
    It is especially important to list the mentors' existing/pending support as evidence that there is adequate support in the training environment for the undergraduate trainees.

16. Facilities/Equipment Description – See Appendix B, part 16.

17. Administrative Documentation – See Appendix B, part 17.
    In addition to the documentation described in Appendix B, provide the following items in the Administrative Documentation section of the proposal submission:

    - A letter of support from the institution indicating a strong commitment to the summer training program.

    - Letters of support from all collaborating mentors demonstrating their commitment to support the breast cancer Undergraduate Summer Training Program.

    Note: Administrative documentation **will not** be accepted separately from the electronic submission. All documents or letters must be signed and then scanned into the proposal prior to submission.

    Proposals lacking required administrative documentation may be considered noncompliant and thus may not be forwarded for review (see Appendix B, part 22).

18. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.
    Funding for these awards can be requested for a $4,000 stipend per student per summer and up to $25,000 per year for administrative costs over a 3-year performance period for a maximum total of $171,000 in direct costs. Training awards frequently have a different institutional indirect charge. Undergraduate Award applicants are encouraged to check with their institution concerning indirect costs. Direct costs can cover tuition, student stipends, faculty salary, and expenses including research supplies. Funding should be requested for the Program Director to attend a one-time, 3½-day meeting to disseminate the results of Department of Defense-sponsored research. Applicants are asked to budget for this meeting in year 2 of the Detailed Cost Estimate Form.

19. Instruments – See Appendix B, part 19.

20. Publications and/or Patent Abstracts – See Appendix B, part 20.

21. Proposal Submission – See Appendix B, part 21.

22. Submission Deadline – See Appendix B, part 22.
    Please note that one electronic PDF version of your proposal must be uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet no later than **11:59 p.m. (applicant's local time) June 12, 2002. Submission of a proposal after the deadline may be grounds for proposal rejection.**

23. Regulatory Compliance and Quality Requirements – See Appendix B, part 23.
    The one-page Certificate of Environmental Compliance and one-page Principal Investigator Safety Program Assurance documents are to be submitted with the proposal. Additional documents related to Regulatory Compliance and Quality issues should be available on the CDMRP web site by April 2002. See Appendix B, part 23 for more details.

Principal Investigator: _____
Last Name *First Name* *MI*

Proposal Title: _____

_____

_____

Undergraduate Summer Training Program Award Proposal
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References (no page limit)	___
Biographical Sketches (3-page limit each)	
Program Director (PI)	___
Participating Staff	___
Named Trainees	___
Existing/Pending Support (no page limit)	___
Facilities/Equipment Description (no page limit)	___
Administrative Documentation (no page limit)	
List of all items included in this section	___
Letter of institutional support	___
Letters of support from all collaborating mentors	___
Detailed Cost Estimate (no page limit)	___
Instruments (no page limit)	___
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Principal Investigator Safety Program Assurance	___

VI. Predoctoral Traineeship Awards

VI-A. Predoctoral Traineeship Awards

The intent of Predoctoral Traineeship Awards is to support promising graduate students studying breast cancer under the guidance of a designated mentor. The overall goal of Predoctoral Traineeship Awards is to prepare individuals for careers in breast cancer research. Individuals enrolled in an M.D./Ph.D. program are encouraged to apply. Important aspects of these applications include (1) the mentor and the training environment, (2) the candidate's qualifications, and (3) the candidate's plans after the completion of the proposed project.

Predoctoral Traineeship Award proposals, with appropriate direction from the mentor, are to be written and signed by the trainee as the Principal Investigator (PI) and author of the proposal. Proposals will not be evaluated nor will awards be made for "to be named" trainees. Predoctoral Traineeship Award applicants must describe the proposed research project, training program, and their career goals in the body of the proposal. The mentor is also responsible for preparing certain components of the proposal. For complete proposal requirements, please refer to Section VI-E. Additional guidance for proposal preparation may be gained by reviewing the peer and programmatic review criteria listed in Sections VI-B and VI-C.

Approximately $5M will be available for Predoctoral Traineeship Awards. Predoctoral Traineeship Awards can be requested for an average of $30,000 per year, inclusive of direct and indirect costs for a maximum of $90,000 over 3 years. Direct costs can cover tuition, stipend, travel to scientific meetings, and expenses (including supplemental research supplies). These awards are intended to support the trainee during dissertation research rather than rotations or basic course work.

Submission of the same research project to the Fiscal Year 2002 Breast Cancer Research Program under different award mechanisms will not be allowed, and all such duplicate submissions may be administratively withdrawn. This includes submissions under different award mechanisms from different PIs. The Government reserves the right to reject any proposal.

VI-B. Scientific Peer Review Evaluation Criteria for Predoctoral Traineeship Award Proposals

Predoctoral Traineeship Award proposals will be evaluated according to the criteria listed below:

- **Candidate:** Do the candidate's achievements to date (as reflected by background, academic performance, awards, and honors) make him or her qualified for predoctoral training? What are the candidate's stated career goals? What are the candidate's research plans after the completion of this project? Do the letters of recommendation support the candidate's abilities and potential for a productive research career?

- **Mentor:** Does the mentor have the background, qualifications, research resources, and time to supervise the candidate's training program? What has been the mentor's previous research training experience with candidates for advanced degrees?

- **Research Training and Environment:** Are the research and training programs properly structured and balanced to ensure that the trainee will acquire the necessary skills and knowledge about the scientific area being studied? Is the research proposed likely to provide the candidate with a strong foundation in breast cancer research that will prepare and encourage him or her to follow a career path in this area? Does the training take place in an environment that is appropriate for accomplishing the candidate's goals? Is there evidence that the research and training requirements are adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed?

- **Relevance:** Does the predoctoral training relate to an important problem in breast cancer research? Is the proposed research likely to train and encourage the candidate to pursue a career in breast cancer research? If the aims of the training are achieved, will the results of the training and research be of benefit to breast cancer research? Does the application make a convincing case for the relevance of the research and training to breast cancer?

- **Budget:** Is the budget appropriate for the work proposed? Are there sufficient overall financial resources to support the proposed research?

VI-C. Programmatic Review Evaluation Criteria for Predoctoral Traineeship Award Proposals

Funding recommendations at this second tier of review are based on a comparative process. Applicants are reminded of the importance of programmatic relevance and the importance of meeting the intent of the Predoctoral Traineeship mechanism. Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.2.

VI-D. Letter of Intent

All applicants considering submission of a proposal in response to this program announcement are requested to submit an electronic Letter of Intent no later than May 30, 2002. This form can be found on the Congressionally Directed Medical Research Programs (CDMRP) web site at http://cdmrp.army.mil/funding/02bcrp2.htm.

VI-E. Proposal Preparation

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for Predoctoral Traineeship Awards. Please note that the body of the proposal is limited to **6 pages,** inclusive of any figures, tables, graphs, and photographs. **Proposals exceeding specified page limits may be administratively withdrawn by the Government prior to peer review.**

Ensure that one electronic Portable Document Format (PDF) version of your proposal, which will serve as the official proposal submission, is uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet no later than **11:59 p.m. (applicant's local time) June 12, 2002.** Applicants are required to submit the Proposal Information prior to upload/submission of the proposal. Applicants are encouraged to begin this part of the submission process early and submit their Proposal Information at least 2 weeks prior to the submission deadline. **Applicants unfamiliar with the preparation and submission of PDF files are encouraged to acquire the software and learn the process well before the submission deadline.**

1. Who May Apply – See Appendix B, part 1.
   Predoctoral Traineeship Awards are made to promising graduate students under the guidance of a designated mentor. Individuals enrolled in an M.D./Ph.D. program are encouraged to apply.

2. Proposal Acceptance Criteria – See Appendix B, part 2.

3. Resubmissions and Duplicate Submissions – See Appendix B, part 3.

4. Proposal Information – See Appendix B, part 4 and Appendix C.

5. Title/Referral Page – See Appendix B, part 5.

6. Table of Contents – See Appendix, part 6.
   Use the table of contents at the end of this section in your proposal submission. This table of contents should be used as a guide for assembling all required components of the proposal. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the proposal that includes the PI's name (last name, first name, middle initial) and proposal log number (this number will be automatically provided when a draft of the Proposal Information is saved; see Appendix C).

7. Checklist for Proposal Submission – See Appendix B, part 7.

8. Proposal Abstracts – See Appendix B, part 8 and Appendix D.

9. Statement of Work – See Appendix B, part 9 and Appendix D.

10. Proposal Relevance Statement – See Appendix B, part 10.
    In addition to the instructions found in Appendix B, part 10, predoctoral candidates should describe explicitly (within the 1-page limit) the training value of the proposed research concept relative to the applicant's career goals and how the proposed research is pertinent to one or more critical issues in breast cancer biology, etiology, prevention, detection, diagnosis, and/or therapy. Articulate how the combination of training and relevance to breast cancer will prepare the candidate for a career in the battle against breast cancer.

11. Proposal Body – See Appendix B, part 11.
    The body of Predoctoral Traineeship Award proposals is limited to **6 pages,** inclusive of figures, tables, graphs, and photographs, if used, and should include descriptions of the training and career plans and the research project as described below.

    Address the following in the body of the proposal:

    a. Career/Research Plans: Briefly describe the applicant's career development plan and how the proposed training will promote the applicant's career development in the area of breast cancer research. Discuss the applicant's research plans after the completion of this award.

    b. Description of Research Project: Describe the proposed project using a general outline including background, hypothesis/rationale/purpose, objectives, and methods.

12. Abbreviations – See Appendix B, part 12.

13. References – See Appendix B, part 13.

14. Biographical Sketches – See Appendix B, part 14 and Appendix E.
    For Predoctoral Traineeship Award proposals, biographical sketches should be prepared for the candidate (the PI), the mentor, and collaborating investigators.

15. Existing/Pending Support – See Appendix B, part 15.
    It is especially important to list the mentor's existing/pending support as evidence that there is adequate support in the training environment for the predoctoral trainee.

16. Facilities/Equipment Description – See Appendix B, part 16.

17. Administrative Documentation – See Appendix B, part 17.
    In addition to the documentation described in Appendix B, provide the following items in the Administrative Documentation section of every copy of the proposal submission:

    - Official transcripts from undergraduate institutions and graduate-level courses completed to date. All foreign language transcripts must be accompanied by an English translation.
    - A letter of support from the **mentor** describing his or her commitment to the

training/career development/mentorship of the applicant.

The mentor should include the following in his or her letter of support:

- A description of the applicant's potential as a future breast cancer researcher;
- A description of the mentor's interaction in training the candidate;
- A description of the training environment;
- A description of the research training in which the applicant will participate, such as coursework, laboratory techniques, conferences, and journal clubs;
- A brief overview of research being performed under his or her direction;
- Information on how the mentor can assist in training the applicant for a career in breast cancer research;
- An outline of the mentor's history in training other predoctoral students; and
- A brief description of the laboratory's resources to demonstrate the adequacy of available support for the trainee's project (specific details on existing support should be covered in the Existing/Pending Support section; see item 15 above).

- Two additional letters of recommendation.

- Letters of support from other collaborating investigators, if applicable.

Note: Administrative documentation **will not** be accepted separately from the electronic submission. All documents or letters must be signed and then scanned into the proposal prior to submission.

Proposals lacking required administrative documentation may be considered noncompliant and thus may not be forwarded for review (see Appendix B, part 22).

18. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.
Predoctoral Traineeship Awards can be requested for an average of $30,000 per year inclusive of direct and indirect costs for a maximum of $90,000 over 3 years. Training awards frequently have a different institutional indirect charge. Predoctoral Traineeship Award applicants are encouraged to check with their institution concerning indirect costs. Direct costs can cover tuition, stipend, textbooks, fees, travel to scientific meetings, and expenses including supplemental research supplies. However, please note that the primary use of these funds should be for salary support, not for fundamental support of the trainee's research project. These awards are intended to support the trainee during dissertation research rather than rotations or basic course work. The amount allotted for travel is $1,500 per year to attend scientific/technical meetings. In addition, funding should be requested for a one-time, 3½-day meeting to disseminate the results of Department of Defense-sponsored research. Applicants are asked to budget for this meeting in year 2 of the Detailed Cost Estimate Form.

19. Instruments – See Appendix B, part 19.

20. Publications and/or Patent Abstracts – See Appendix B, part 20.

21. Proposal Submission – See Appendix B, part 21.

22. Submission Deadlines – See Appendix B, part 22.
    Please note that one electronic PDF version of your proposal must be uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet no later than **11:59 p.m. (applicant's local time) June 12, 2002. Submission of a proposal after the deadline may be grounds for proposal rejection.**

23. Regulatory Compliance and Quality Requirements – See Appendix B, part 23.
    The one-page Certificate of Environmental Compliance and one-page Principal Investigator Safety Program Assurance documents are to be submitted with the proposal. Additional documents related to Regulatory Compliance and Quality issues should be available on the CDMRP web site by April 2002. See Appendix B, part 23 for more details.

Principal Investigator: _____
Last Name *First Name* *MI*

Proposal Title: _____

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Proposal Body (6-page limit) ..... ___
Abbreviations (1-page limit) ..... ___
References (no page limit) ..... ___
Biographical Sketches (3-page limit each)
- PI (Predoctoral Applicant) ..... ___
- Mentor ..... ___
- Collaborating Investigators ..... ___

Existing/Pending Support (no page limit) ..... ___
Facilities/Equipment Description (no page limit) ..... ___
Administrative Documentation (no page limit)
- List of all items included in this section ..... ___
- Transcripts ..... ___
- Letter of support from the mentor ..... ___
- Letters of recommendation (2) ..... ___
- Letters of support from collaborating individuals and/or institutions ..... ___

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VII. Postdoctoral Traineeship Awards

VII-A. Postdoctoral Traineeship Awards

The intent of Postdoctoral Traineeship Awards is to enable recent medical or other doctoral degree graduates to obtain the necessary experience to pursue a career in breast cancer research. Eligible applicants should have been in the laboratory in which this research is to be performed no more than 2 years at the time of submission and should have a total of less than 5 years of postdoctoral research experience (exclusive of clinical residency or fellowship training).

Postdoctoral Traineeship proposals should either extend the candidate's ongoing research related to breast cancer or broaden the scope of his or her research to include work relevant to breast cancer, under the guidance of a designated mentor. The research focus of the proposal should address an issue relevant to breast cancer biology, etiology, prevention, detection, diagnosis, and/or therapy. Individuals with any doctoral degree are encouraged to apply.

The overall goal of Postdoctoral Traineeship Awards is to prepare individuals for careers in breast cancer research. Important aspects of these applications include (1) the mentor and the training environment, (2) the candidate's qualifications, and (3) the candidate's plans after the completion of the proposed project.

Postdoctoral Traineeship proposals, with appropriate direction from the mentor, are to be written and signed by the trainee as the Principal Investigator (PI) and author of the proposal. Proposals will not be evaluated nor will awards be made for "to be named" trainees. Postdoctoral Traineeship applicants must describe their research project, training program, and goals in the body of the proposal. The mentor is also responsible for preparing certain components of the proposal. For complete proposal requirements, please refer to Section VII-E. Additional guidance for proposal preparation may be gained by reviewing the peer and programmatic review criteria listed in Sections VII-B and VII-C.

Approximately $10M will be available for Postdoctoral Traineeship Awards. Traineeships can be requested for an average of $57,000 per year, inclusive of direct and indirect costs, for a maximum of $171,000 over 3 years. Direct costs can cover salary, travel to scientific meetings, and expenses including supplemental research supplies.

Submission of the same research project to the Fiscal Year 2002 (FY02) Breast Cancer Research Program (BCRP) under different award mechanisms will not be allowed, and all such duplicate submissions may be administratively withdrawn. This includes submissions under different award mechanisms from different PIs. The Government reserves the right to reject any proposal.

VII-B. Scientific Peer Review Evaluation Criteria for Postdoctoral Traineeship Award Proposals

Postdoctoral Traineeship Award proposals will be evaluated according to the following criteria:

- **Candidate:** Do the candidate's achievements to date (as assessed by background, academic performance, awards, and honors) make him or her well qualified for postdoctoral training? Does the candidate have a record of previous research experience, publications, and/or related professional training that indicates suitability for a career in breast cancer research? What are the candidate's research plans after the completion of this project? Has the candidate demonstrated a personal commitment to pursuing a career in breast cancer research? Do the letters of recommendation support the candidate's abilities and potential for a productive research career?

- **Mentor:** Does the mentor have the background, qualifications, research resources, and time to supervise the candidate's training program? What is the mentor's previous research training experience with doctoral students, fellows, residents, etc.?

- **Relevance:** Does the training relate to an important problem in breast cancer research? Is the proposed research likely to train and encourage the candidate to pursue a career in breast cancer research? If the aims of the training are achieved, will the results of the training and research be of benefit to breast cancer research? Does the application make a convincing case for the relevance of the research to breast cancer?

- **Training and Environment:** Will the training result in a valuable experience for the trainee in preparing him or her for an independent career in breast cancer research? Does the postdoctoral training take place in an environment that is appropriate to accomplishing the candidate's goals? Is there evidence that the research requirements are adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed? Is there a strong institutional commitment to research training in breast cancer?

- **Research Strategy:** Are the conceptual framework, hypotheses, design, methods, and analyses adequately developed and well integrated to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative methods/tactics? Has a sound scientific rationale been presented through a critical review and analysis of the literature, logical reasoning, and/or the use of preliminary data? If the research plan requires statistical analysis, is there a clear statistical plan with power analysis included in the proposal?

- **Budget:** Is the budget appropriate for the work proposed? Are there sufficient overall financial resources to support the proposed research?

VII-C. Programmatic Review Evaluation Criteria for Postdoctoral Traineeship Award Proposals

Funding recommendations at this second tier of review are based on a comparative process. Applicants are reminded of the importance of programmatic relevance and the importance of meeting the intent of the Postdoctoral Traineeship Award mechanism. Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.2.

VII-D. Letter of Intent

All applicants considering submission of a proposal in response to this program announcement are requested to submit an electronic Letter of Intent no later than May 30, 2002. This form can be found on the Congressionally Directed Medical Research Programs (CDMRP) web site at http://cdmrp.army.mil/funding/02bcrp2.htm.

VII-E. Proposal Preparation

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for Postdoctoral Traineeship Awards. Please note that the body of the proposal is limited to **6 pages,** inclusive of any figures, tables, graphs, and photographs. **Proposals exceeding specified page limits may be administratively withdrawn by the Government prior to peer review.**

Ensure that one electronic Portable Document Format (PDF) version of your proposal, which will serve as the official proposal submission, is uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet no later than **11:59 p.m. (applicant's local time) June 12, 2002.** Applicants are required to submit the Proposal Information prior to upload/submission of the proposal. Applicants are encouraged to begin this part of the submission process early and submit their Proposal Information at least 2 weeks prior to the submission deadline. **Applicants unfamiliar with the preparation and submission of PDF files are encouraged to acquire the software and learn the process well before the submission deadline.**

1. Who May Apply – See Appendix B, part 1 and item 17 on page VII-5.
   Eligible applicants should have been in the laboratory in which the research is to be performed no more than 2 years at the time of submission and should have less than 5 years total of postdoctoral research experience (exclusive of clinical residency or fellowship training). Individuals who will have received any doctoral degree by the time of award negotiation may apply.

2. Proposal Acceptance Criteria – See Appendix B, part 2.

3. Resubmissions and Duplicate Submissions – See Appendix B, part 3.

4. Proposal Information – See Appendix B, part 4 and Appendix C.

5. Title/Referral Page – See Appendix B, part 5.

6. Table of Contents – See Appendix B, part 6.
   Use the table of contents on page VII-8 in your proposal submission. This table of contents should be used as a guide for assembling all required components of the proposal. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the proposal that includes the PI's name (last name, first name, middle initial) and proposal log number (this number will be automatically provided when a draft of the Proposal Information is saved; see Appendix C).

7. Checklist for Proposal Submission – See Appendix B, part 7.

8. Proposal Abstracts – See Appendix B, part 8 and Appendix D.

9. Statement of Work – See Appendix B, part 9 and Appendix D.

10. Proposal Relevance Statement – See Appendix B, part 10.
    In addition to the instructions found in Appendix B, part 10, Postdoctoral Traineeship Award applicants should describe explicitly (within the 1-page limit) the training value of the proposed research concept relative to the applicant's career goals and how the proposed research is pertinent to one or more critical issues in breast cancer biology, etiology, prevention, detection, diagnosis, and/or therapy. Articulate how the combination of training and relevance to breast cancer will prepare the candidate for a career in the battle against breast cancer.

11. Proposal Body – See Appendix B, part 11.
    The body of Postdoctoral Traineeship proposals is limited to **6 pages,** inclusive of figures, tables, graphs, and photographs, if used, and should include descriptions of the training, career plans, and the research project as described below.

    a. Description of the Research Training: Describe the research training in which the candidate will participate such as coursework, laboratory techniques, conferences, and journal clubs.

    b. Career/Research Plans: Briefly describe the applicant's career development plan and how the proposed training will promote the trainee's career development in the area of breast cancer research. Discuss the applicant's research plans after the completion of this award.

    c. Description of Research Project: Describe the proposed project using the general outline provided below:

i. Background: Briefly describe the ideas behind the proposed work and cite relevant literature references.

ii. Hypothesis/Rationale/Purpose: State the hypothesis to be tested and the expected results.

iii. Objectives: State concisely the specific aims and the research strategy of the project.

iv. Methods: Give details about the experimental design and methodology.

12. Abbreviations – See Appendix B, part 12.

13. References – See Appendix B, part 13.

14. Biographical Sketches – See Appendix B, part 14 and Appendix E.
For Postdoctoral Traineeship proposals, biographical sketches should be prepared for the applicant, the mentor, and collaborating investigators.

15. Existing/Pending Support – See Appendix B, part 15.
It is especially important to list the mentor's existing/pending support as evidence that there is adequate support in the training environment for the postdoctoral trainee.

16. Facilities/Equipment Description – See Appendix B, part 16.

17. Administrative Documentation – See Appendix B, part 17.
In addition to the documentation described in Appendix B, provide the following items in the Administrative Documentation section of the proposal submission:

- Official transcripts from undergraduate and graduate institutions. All foreign language transcripts must be accompanied by an English translation.

- A form signed by the Department Chair, Dean, or equivalent official verifying that the applicant (1) has or will have successfully completed a doctoral or medical degree at the time of award negotiation, (2) has been in the laboratory in which this research is to be performed no more than 2 years at the time of submission, and (3) has a total of less than 5 years of postdoctoral research experience (exclusive of clinical residency or fellowship training) and therefore is an eligible applicant for this award type. Use the Statement of Eligibility Form at the end of this section.

- A letter of support from the **mentor** describing his or her commitment to the training/career development/mentorship of the applicant.

- The mentor should include the following in his or her letter of support:
  - A description of the applicant's potential as a future breast cancer researcher;
  - A description of the mentor's interaction in training the candidate;
  - A description of the training environment;
  - Information on how the mentor can assist in training the applicant for a career in breast cancer research;
  - An outline of the mentor's history in training other postdoctoral students; and
  - A brief description of the laboratory's resources to demonstrate the adequacy of available support for the trainee's project (specific details on existing support should be covered in the Existing/Pending Support section; see item 15 above).

- Two additional letters of recommendation.

- Letters of support from other collaborating investigators, if applicable.

Note: Administrative documentation **will not** be accepted separately from the electronic submission. All documents or letters must be signed and then scanned into the proposal prior to submission.

Proposals lacking required administrative documentation may be considered noncompliant and thus may not be forwarded for review (see Appendix B, part 22).

18. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.
    Postdoctoral Traineeship Awards can be requested for an average of $57,000 per year, inclusive of direct and indirect costs, for a maximum of $171,000 over 3 years. Training awards frequently have a different institutional indirect charge. Postdoctoral Traineeship Award applicants are encouraged to check with their institution concerning indirect costs. Direct costs can cover salary, travel to scientific meetings, and expenses including supplemental research supplies. However, please note that the primary use of these funds should be for salary support, not for support of the trainee's research project. The amount allotted for travel is $1,500 per year to attend scientific/technical meetings. In addition, funding should be requested for a one-time, 3½-day meeting to disseminate the results of Department of Defense-sponsored research. Applicants are asked to budget for this meeting in year 2 of the Detailed Cost Estimate Form.

19. Instruments – See Appendix B, part 19.

20. Publications and/or Patent Abstracts – See Appendix B, part 20.

21. Proposal Submission – See Appendix B, part 21.

22. Submission Deadlines – See Appendix B, part 22.
    Please note that one electronic PDF version of your proposal must be uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet no later than **11:59 p.m. (applicant's local time) June 12, 2002. Submission of a proposal after the deadline may be grounds for proposal rejection.**

23. Regulatory Compliance and Quality Requirements – See Appendix B, part 23.
    The one-page Certificate of Environmental Compliance and one-page Principal Investigator Safety Program Assurance documents are to be submitted with the proposal. Additional documents related to Regulatory Compliance and Quality issues should be available on the CDMRP web site by April 2002. See Appendix B, part 23 for more details.

Principal Investigator: _____
Last Name *First Name* *MI*

Proposal Title: _____

_____

Postdoctoral Traineeship Award
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References (no page limit) ..... ___
Biographical Sketches (3-page limit each)
- PI (Postdoctoral Applicant) ..... ___
- Mentor ..... ___
- Collaborating Investigators ..... ___

Existing/Pending Support (no page limit) ..... ___
Facilities/Equipment Description (no page limit) ..... ___
Administrative Documentation (no page limit)
- List of all items included in this section ..... ___
- Transcripts ..... ___
- Statement of Eligibility Form ..... ___
- Letter of support from the mentor ..... ___
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Publications and/or Patent Abstracts (5-document limit) ..... ___
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Principal Investigator Safety Program Assurance ..... ___

STATEMENT OF ELIGIBILITY

Department of Defense
FY02 Breast Cancer Research Program
Postdoctoral Traineeship Award

Applicant's Name: _____

Title of Proposal: _____

I certify that the above-named investigator fulfills the following requirements to be considered for a Postdoctoral Traineeship Award and specifically meets all of the following criteria:

- Has or will have successfully completed a doctoral thesis or medical degree at the time of award negotiation;
- Has 2 years or less of postdoctoral experience in the laboratory in which the proposed research will be performed; and
- Has a total of less than 5 years of postdoctoral research experience (exclusive of clinical residency or fellowship training at the time of proposal submission.

Name of Official (*please print):* _____

Title: _____

Organization: _____

Signature of Official: _____ Date: _____

VIII. Clinical Research Nurse Awards

VIII-A. Clinical Research Nurse Awards

Nurses are assuming more active roles in the testing of clinical therapeutics, often providing not only clinical trial management and protocol adherence but also patient education. Therefore, the training of clinical research nurses requires a complete, interdisciplinary clinical research experience. The intent of the Clinical Research Nurse Awards is to facilitate the preparation of nurses for active careers in breast cancer research and testing. Eligible applicants should have a bachelor, masters, or doctoral degree in nursing with an interest in breast cancer clinical research.

The overall goal of Clinical Research Nurse Awards is to prepare nurses for the breast cancer clinical research profession through mentored research training. Important aspects of these applications include (1) the mentor; (2) the structured, interdisciplinary clinical research training environment; (3) the candidate's qualifications; and (4) the candidate's plans after the completion of the proposed project.

The extent of the project involvement, autonomy, and responsibility of the trainee should be commensurate with his or her education level and experience. Training through this award may, but is not required to, result in attainment of a more advanced degree. A Clinical Research Nurse Award will require the active involvement of a mentor from any health care profession (e.g., nurse researcher, physician, research psychologist). The primary criterion for selection of the mentor is that he or she be an established researcher with experience in conducting breast cancer clinical research who can provide the trainee with a supportive training environment. The mentor must be able to dedicate sufficient time to the trainee so that a balanced clinical research training program is provided.

Clinical Research Nurse Award proposals, with appropriate direction and input from the mentor, should be written and signed by the trainee as the Principal Investigator (PI) and author of the proposal. Proposals will not be evaluated nor will awards be made for "to be named" trainees. Clinical Research Nurse Award applicants must describe an interdisciplinary training program that can cover the spectrum of breast cancer care from screening and early detection to palliative care for women with breast cancer through coursework, experience with patients, and participation in a research project. The training curriculum could include a study of topics relevant to breast cancer clinical research including research design, methodology, quality assurance and safety, essential protection of human subjects' information, basic clinical trial management, and data analysis. Because of the nature of this training and resources that may or may not be available in different regions, trainees can consider building their own curriculum by taking advantage of seminars and courses offered at various locations. The trainee must describe his or her role in an active research project under the auspices of the mentor. The long-term career goals of the applicant and how these goals relate to breast cancer research must also be discussed in the body of the proposal. The mentor is also responsible for preparing certain

components of the proposal. For complete proposal requirements, please refer to Section VIII-E. Additional guidance for proposal preparation may be gained by reviewing the peer and programmatic review criteria listed in Sections VIII-B and VIII-C.

Approximately $5M will be available for Clinical Research Nurse Awards. The awards can be requested for up to $100,000 per year inclusive of direct and indirect costs for a period of 2 years. Of this amount, up to $75,000 per year may be requested for salary support and up to $25,000 per year for support of tuition, textbooks, fees, travel to scientific meetings, and supplemental research supplies. The amount allotted for travel is $1,800 per year to attend scientific/technical meetings. Institutional matching or supplementation of salary during the training period is encouraged.

Submission of the same research project to the Fiscal Year 2002 Breast Cancer Research Program under different award mechanisms will not be allowed, and all such duplicate submissions may be administratively withdrawn. This includes submissions under different award mechanisms from different PIs. The Government reserves the right to reject any proposal.

VIII-B. Scientific Peer Review Evaluation Criteria for Clinical Research Nurse Award Proposals

Clinical Research Nurse Award proposals will be evaluated according to the following criteria:

- **Candidate:** Do the candidate's achievements to date (as assessed by background, academic performance, work experience, letters of recommendation, awards, and/or honors) make him or her well qualified for clinical research training? Does the candidate have a record of previous interest or experience that indicates suitability for a career in clinical breast cancer research? What are the candidate's career plans after the completion of this training? Has the candidate demonstrated a personal commitment to pursuing a career in clinical breast cancer research?

- **Mentor:** Does the mentor have the background, qualifications, and time to supervise the candidate's training program? Does the mentor have a strong record in clinical breast cancer research involving screening and detection, early treatment, survivorship, or palliative care of patients? What is the mentor's previous research training experience with nurses, doctoral students, fellows, residents, etc.?

- **Clinical Research Training:** Is the proposed training program both didactic and experiential in nature? Are the clinical research training and structured study programs properly balanced to ensure that the trainee will acquire the necessary skills and knowledge? Will the research project result in a valuable experience for the trainee in preparing him or her for a career in breast cancer clinical research? Is the training program interdisciplinary?

- **Relevance:** Is the proposed research training likely to instruct and encourage the candidate to pursue a career in breast cancer research? If the aims of the training are achieved, will the results of the training and research be of benefit to breast cancer research?

- **Environment:** Does the training take place in an interdisciplinary environment that is appropriate to accomplishing the candidate's goals? Is there evidence that the clinical research requirements are adequately supported by the scientific environment, necessary resources, and any collaborative arrangements proposed? Is there a strong institutional commitment to training in breast cancer?

- **Budget:** Is the budget appropriate for the training proposed? Are there sufficient overall financial resources available to support the proposed training?

VIII-C. Programmatic Review Evaluation Criteria for Clinical Research Nurse Award Proposals

Funding recommendations at this second tier of review are based on a comparative process. Applicants are reminded of the importance of programmatic relevance and the importance of meeting the intent of the Clinical Research Nurse Award mechanism. Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.2.

VIII-D. Letter of Intent

All applicants considering submission of a proposal in response to this program announcement are requested to submit an electronic Letter of Intent no later than May 30, 2002. This form can be found on the Congressionally Directed Medical Research Programs (CDMRP) web site at http://cdmrp.army.mil/funding/02bcrp2.htm.

VIII-E. Proposal Preparation

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for Clinical Research Nurse proposals. Please note that the body of the proposal is limited to **6 pages,** inclusive of any figures, tables, graphs, and photographs. **Proposals exceeding specified page limits may be administratively withdrawn by the Government prior to peer review.**

Ensure that one electronic Portable Document Format (PDF) version of your proposal, which will serve as the official proposal submission, is uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet no later than **11:59 p.m. (applicant's local time) June 12, 2002.** Applicants are required to submit the Proposal Information prior to upload/submission of the proposal. Applicants are encouraged to begin this part of the submission process early and

submit their Proposal Information at least 2 weeks prior to the submission deadline. **Applicants unfamiliar with the preparation and submission of PDF files are encouraged to acquire the software and learn the process well before the submission deadline.**

1. Who May Apply – See Appendix B, part 1 and item 17 on page VIII-6.
   Eligible applicants should have completed a bachelor, masters, or doctoral level degree in nursing at the time of award negotiation and should have a current nursing license.

2. Proposal Acceptance Criteria – See Appendix B, part 2.

3. Resubmissions and Duplicate Submissions – See Appendix B, part 3.

4. Proposal Information – See Appendix B, part 4 and Appendix C.

5. Title/Referral Page – See Appendix B, part 5.

6. Table of Contents – See Appendix B, part 6.
   Use the table of contents at the end of this section in your proposal submission. This table of contents should be used as a guide for assembling all required components of the proposal. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the proposal that includes the PI's name (last name, first name, middle initial) and proposal log number (this number will be automatically provided when a draft of the Proposal Information is saved; see Appendix C).

7. Checklist for Proposal Submission – See Appendix B, part 7.

8. Proposal Abstracts – See Appendix B, part 8 and Appendix D.

9. Statement of Work – See Appendix B, part 9 and Appendix D.

10. Proposal Relevance Statement – See Appendix B, part 10.
    In addition to the instructions found in Appendix B, part 10, Clinical Research Nurse Award applicants should describe explicitly (within the 1-page limit) the training value of the proposed clinical experience relative to the applicant's career goals. Articulate how the combination of training and relevance to breast cancer will prepare the candidate for a career in the battle against breast cancer.

11. Proposal Body – See Appendix B, part 11.
    The body of Clinical Research Nurse Award proposals is limited to **6 pages,** inclusive of figures, tables, graphs, and photographs, if used, and should include descriptions of the training, career plans, and clinical research project, as described below.

a. Description of the Research Training: Describe the research training in which the candidate will participate. Indicate how the training is interdisciplinary. Include any relevant research participation, coursework, seminars, conferences, and journal clubs. Provide a brief statement of the mentor's qualifications, including experience as a clinical supervisor. Describe other members of the research team and how they will they interact with and instruct the candidate.

b. Career/Research Plans: Briefly describe the applicant's career development plan and how the proposed training will promote the trainee's career development in the area of breast cancer clinical research by enhancing his or her knowledge of breast cancer issues and his or her care of breast cancer patients and their families. Discuss the applicant's plans after the completion of this award.

c. Description of Research Project: Describe the proposed project, and the applicant's role in it, in sufficient detail for the project to be evaluated in the context of the complete training program. The degree of detail should be appropriate to the educational background of the applicant, i.e., a Ph.D. candidate should be able to describe aspects of the research strategy in greater depth than an applicant with a bachelor's degree candidate. Use the general outline provided below:

    i. Background and Objectives: Briefly describe the ideas behind the proposed research and state concisely the specific aims (and the research strategy, as appropriate for the applicant) of the project. Bachelor degree level applicants may describe the aims of their proposed training rather than the aims of the project.

    ii. Trainee's Role in the Research Project: Describe the role of the trainee in the proposed research project.

    iii. Value: Describe how this research experience will enhance the applicant's research skills.

12. Abbreviations – See Appendix B, part 12.

13. References – See Appendix B, part 13.

14. Biographical Sketches – See Appendix B, part 14 and Appendix E.
    For Clinical Research Nurse proposals, biographical sketches should be prepared for the applicant, the mentor, and collaborating investigators.

15. Existing/Pending Support – See Appendix B, part 15.
    It is especially important to list the mentor's existing/pending support as evidence that there is adequate support in the clinical training environment for the trainee.

16. Facilities/Equipment Description – See Appendix B, part 16.
    It is critical that both the practice environment and the research environment be clearly and fully described.

17. Administrative Documentation – See Appendix B, part 17.
    In addition to the documentation described in Appendix B, provide the following items in the Administrative Documentation section of the proposal submission:

    - Official transcripts from undergraduate and graduate institutions. All foreign language transcripts must be accompanied by an English translation.

    - A copy of the applicant's current nursing license.

    - A letter of support from the **mentor** describing his or her commitment to the training/career development/mentorship of the applicant.

      The mentor should also include the following in his or her letter of support:
      - A description of the applicant's potential as a future breast cancer researcher;
      - A description of the mentor's interaction in training the candidate;
      - A description of the training environment;
      - A brief overview of other clinical research being performed under his or her direction;
      - Information on how the mentor can assist in training the applicant for a career in breast cancer research;
      - An outline of the mentor's history in clinical research and training; and
      - A brief description of the group's resources to demonstrate the adequacy of available support for the trainee and the project (specific details on existing support should be covered in the Existing/Pending Support section; see item 15 above).

    - Two additional letters of recommendation.

    - Letters of support from other collaborating investigators, if applicable.

    Note: Administrative documentation **will not** be accepted separately from the electronic submission. All documents or letters must be signed and then scanned into the proposal prior to submission.

    Proposals lacking required administrative documentation may be considered noncompliant and thus may not be forwarded for review (see Appendix B, part 22).

18. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.
    Clinical Research Nurse Awards can be requested for up to $100,000 per year inclusive of direct and indirect costs for a period of 2 years. Of this amount, up to $75,000 per year of salary support, and up to $25,000 per year for support of tuition, textbooks, fees, travel to scientific meetings, and supplemental research supplies may be requested. Institutional

matching or supplementation of salary during the training period is encouraged. Training awards frequently have a different institutional indirect charge. Clinical Research Nurse Award applicants are encouraged to check with their institution concerning indirect costs. The amount allotted for travel is $1,800 per year to attend scientific/technical meetings. In addition, funding should be requested for a one-time, 3½-day meeting to disseminate the results of Department of Defense-sponsored research. Applicants are asked to budget for this meeting in year 2 of the Detailed Cost Estimate Form.

19. Instruments – See Appendix B, part 19.

20. Publications and/or Patent Abstracts – See Appendix B, part 20.

21. Proposal Submission – See Appendix B, part 21.

22. Submission Deadlines – See Appendix B, part 22.
    Please note that one electronic PDF version of your proposal must be uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet no later than **11:59 p.m. (applicant's local time) June 12, 2002. Submission of a proposal after the deadline may be grounds for proposal rejection.**

23. Regulatory Compliance and Quality Requirements – See Appendix B, part 23.
    The one-page Certificate of Environmental Compliance and one-page Principal Investigator Safety Program Assurance documents are to be submitted with the proposal. Additional documents related to Regulatory Compliance and Quality issues should be available on the CDMRP web site by April 2002. See Appendix B, part 23 for more details.

Principal Investigator: _____
Last Name *First Name* *MI*

Proposal Title: _____

_____

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Biographical Sketches (3-page limit each)
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- Mentor ..... ___
- Collaborating investigators ..... ___

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- Letters of support from collaborating individuals and/or institutions ..... ___

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IX. Physician-Scientist Training Awards

IX-A. Physician-Scientist Training Awards

There is an urgent need to train physicians as breast cancer clinical researchers. Often, because of competing demands for a physician's time and the need to repay medical school costs, young physicians are not able to pursue clinical research careers. The intent of the Physician-Scientist Training Award is to address the critical shortage of physicians performing clinical breast cancer research.

Eligible applicants for the Physician-Scientist Training Award are physicians in the last year of oncology graduate medical education or within the first 3 years as a junior faculty member. This award is intended to provide a mentored training experience that will prepare physicians for active careers in clinical breast cancer research. The training program may include formal coursework and seminars that should provide the Principal Investigator (PI) with experience in key clinical research areas such as statistics, bioethics, molecular biology, and clinical trial design. The training must take place at an institution or organization within the U.S. at which clinical research is performed. Key elements of this award are the involvement of a mentor with an established cancer research program with an emphasis in clinical breast cancer research and the aggressive protection of the PI's time. In addition, a key provision will be demonstration by the PI of an ongoing commitment to clinical breast cancer research. For the purposes of this award, breast cancer clinical research is defined as patient-oriented research involving human subjects or material of human origin (e.g., tissue specimens); research should involve direct interaction with human subjects and have demonstrable potential to impact prevention or treatment of breast cancer.

Physician-Scientist Training Award proposals should include a discussion of the level of institutional commitment to fostering the applicant's clinical breast cancer research career as reflected by (1) the extent the applicant will be relieved of his or her academic and/or other clinical responsibilities to have additional time for research, (2) the provision of adequate laboratory facilities and equipment to support the clinical research requirements, and (3) the opportunities for critical professional interaction with senior colleagues. **A letter of support from the institution must be included as part of the proposal.**

Approximately $8M will be available for Physician-Scientist Training Awards. The awards require a 5-year commitment to clinical breast cancer research and consist of two phases. During the initial phase, the first 3 years of the award, both salary support and a medical school debt reduction incentive are provided. The final 2-year phase provides continued medical school debt reduction payments contingent on the PI's ongoing commitment to clinical breast cancer research. The total support that can be requested over the life of the award is $700,000 inclusive of direct, indirect, and tuition debt reduction costs.

Salary support under this award can be requested for up to 60% of the PI's and for up to 50% of a key support person's salary (e.g., a research nurse or a data manager) for up to 3 years plus indirect costs as appropriate. Direct costs can cover only salary support and travel to scientific/technical meetings. Funds for other research expenses must be provided from another resource (e.g., a grant to the mentor). Evidence of either current or pending research support from any funding source is a requirement of a Physician-Scientist Training Award and will be required at the time of award negotiation. Institutional commitment must demonstrate a minimum of 60% protection of the PI's time.

Up to $40,000 per year (representing no more than the actual loan repayments made by the PI during the year) can be requested for repayment of qualifying medical school education loans over the 5-year performance period of the award. Upon completion of the 5-year commitment to clinical breast cancer research, an additional payment will be made to cover the remainder of the medical school education loan(s), up to a total of $200,000 for loan repayment over the 5-year period. For example, a PI with a total medical school education loan of $100,000 principal and annual payments of $18,000 would receive $18,000 per year for the 5 years of the award. Just prior to the end of the performance period, an additional payment equal to the remaining debt of the original loan would be made. Qualifying loans include funds borrowed from the Government, academic institutions, or commercial lenders for medical school tuition expenses at an accredited U.S. medical or osteopathic school, additional educational expenses (e.g., textbooks, supplies, fees), and reasonable living expenses. For more information on qualifying loans, refer to Section IX-E, item 18.

Submission of the same research project to the Fiscal Year 2002 (FY02) Breast Cancer Research Program (BCRP) under different award mechanisms will not be allowed, and all such duplicate submissions may be administratively withdrawn. This includes submissions under different award mechanisms from different PIs. The Government reserves the right to reject any proposal.

IX-B. Scientific Peer Review Evaluation Criteria for Physician-Scientist Training Award Proposals

Physician-Scientist Training Award proposals will be evaluated according to the following criteria:

- **Candidate:** Does the candidate have the appropriate background to pursue a career in breast cancer clinical research? Do the candidate's previous training and prior research experience indicate promising achievements to date? Is there a need for the proposed research experience and training in order for the candidate to develop into an independent breast cancer investigator?

- **Potential for a Career in Breast Cancer Clinical Research:** Has the candidate demonstrated how his or her qualifications, the mentor, the training environment, the quality of research training, and the project's scientific relevance will lead to a career in breast cancer clinical research? Has the candidate demonstrated a personal commitment to pursuing a career in breast cancer clinical research?

- **Mentor:** Does the mentor have the background, qualifications, research resources, and time to supervise the candidate's training program? What is the mentor's previous research training experience with doctoral students, fellows, residents, etc.? Does the mentor have an established cancer research program with an emphasis on clinical breast cancer research?

- **Clinical Research Training Program:** Is there a clearly described training program in breast cancer clinical research? Does the training program include key clinical research areas such as statistics, bioethics, molecular biology and clinical trials design? Are the conceptual framework, hypotheses, design, methods, and analyses of the research adequately developed and well integrated for the candidate's research program? Is the candidate aware of potential problem areas and are potential solutions proposed? Will the research offer a valuable opportunity to further develop research experience to advance and develop the candidate's independent clinical breast cancer research career?

- **Disease Relevance:** Does the candidate's research program address a critical problem in breast cancer research? Does the application make a convincing case for the relevance of the research to breast cancer? To what extent will the project, if successful, make an original and important contribution to the goal of preventing or eradicating breast cancer and/or advancing research in the field?

- **Institutional Commitment:** Is there a strong institutional commitment to relieve the candidate from other academic or clinical responsibilities in order to permit a minimum of 60% effort for research activities? Is the institution prepared to provide adequate laboratory facilities, equipment, and opportunities for critical professional interaction with senior colleagues? Is there a strong institutional commitment to the candidate's development?

- **Budget:** Is the budget appropriate?

IX-C. Programmatic Review Evaluation Criteria for Physician-Scientist Training Award Proposals

Funding recommendations at this second tier of review are based on a comparative process. Applicants are reminded of the importance of programmatic relevance and the importance of meeting the intent of the Physician-Scientist Training Award mechanism. Additional details on programmatic review procedures and evaluation criteria are included in Section I-C.2.

IX-D. Letter of Intent

All applicants considering submission of a proposal in response to this program announcement are requested to submit an electronic Letter of Intent no later than May 30, 2002. This form can be found on the Congressionally Directed Medical Research Programs (CDMRP) web site at http://cdmrp.army.mil/funding/02bcrp2.htm.

IX-E. Proposal Preparation

Instructions for proposal preparation for all award mechanisms are found in Appendix B. The following supplemental information is specific for Physician-Scientist Training Awards. Please note that the body of the proposal is limited to **6 pages**, inclusive of any figures, tables, graphs and photographs. **Proposals exceeding specified page limits may be administratively withdrawn by the Government prior to peer review.**

Ensure that one electronic Portable Document Format (PDF) version of your proposal, which will serve as the official proposal submission, is uploaded/submitted by an Authorized Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet no later than **11:59 p.m. (applicant's local time) June 12, 2002.** Applicants are required to submit the Proposal Information prior to upload/submission of the proposal. Applicants are encouraged to begin this part of the submission process early and submit their Proposal Information at least 2 weeks prior to the submission deadline. **Applicants unfamiliar with the preparation and submission of PDF files are encouraged to acquire the software and learn the process well before the submission deadline.**

1. Who May Apply – See Appendix B, part 1.
   Physician-Scientist Training Award applicants must be U.S. citizens, nationals, or permanent residents.

2. Proposal Acceptance Criteria – See Appendix B, part 2.

3. Resubmissions and Duplicate Submissions – See Appendix B, part 3.

4. Proposal Information – See Appendix B, part 4 and Appendix C.

5. Title/Referral Page – See Appendix B, part 5.

6. Table of Contents – See Appendix B, part 6.
   Use the table of contents on page IX-9 in your proposal submission. This table of contents should be used as a guide for assembling all required components of the proposal. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the proposal that includes the PI name (last name, first name, middle initial) and proposal log number (this number will be automatically provided when a draft of the Proposal Information is saved; see Appendix C).

7. Checklist for Proposal Submission – See Appendix B, part 7.

8. Proposal Abstracts – See Appendix B, part 8 and Appendix D.

9. Statement of Work – See Appendix B, part 9 and Appendix D.

10. Proposal Relevance Statement – See Appendix B, part 10.
    Applicants should articulate how the combination of training value and relevance to breast cancer will facilitate the applicant's transition to a career in breast cancer clinical research.

11. Proposal Body – See Appendix B, part 11.
    The body of Physician-Scientist Training Award proposals is limited to **6 pages,** inclusive of figures, tables, graphs, and photographs, if used.

    a. Training Plans: Briefly describe the candidate's training plan and how the proposed experience and training will promote the candidate's transition into a career in breast cancer clinical research. Discuss the applicant's career/research plans after the completion of this award.

    b. Description of Research Project(s): The applicant should provide an overview of how his or her time will be spent once relieved from other academic or clinical responsibilities. The following general outline should be used to describe the research project.

        i. Background: Briefly describe the ideas behind the proposed work and cite relevant literature references.

        ii. Hypothesis/Rationale/Purpose: State the hypothesis that will be tested (in an appropriately designed clinical trial, if applicable) and the expected results.

        iii. Objectives: State concisely the specific aims of the project.

        iv. Methods: Give an overview of the experimental design and methodology including an appropriately powered statistical analysis, if applicable.

12. Abbreviations – See Appendix B, part 12.

13. References – See Appendix B, part 13.

14. Biographical Sketches – See Appendix B, part 14 and Appendix E.
    For Physician-Scientist Training Award proposals, biographical sketches should be prepared for the applicant, the mentor, and collaborating investigators.

15. Existing/Pending Support – See Appendix B, part 15.
    Funds for research support are a requirement of the Physician-Scientist Training Award proposal. List all existing or pending research support of the mentor and the applicant.

16. Facilities/Equipment Description – See Appendix B, part 16.

17. Administrative Documentation – See Appendix B, part 17.
    In addition to the documentation described in Appendix B, provide the following items in the Administrative Documentation section of the proposal submission:

    - A form signed by the Department Chair, Program Director, or Dean indicating that the PI is an eligible applicant for this award type. Use the Statement of Eligibility Form at the end of this section.

    - Proof of U.S. citizenship or permanent resident status (e.g., birth certificate, Permanent Resident Card).

    - A letter of institutional support indicating the level of institutional commitment to fostering the applicant's research career, as reflected by (1) the extent to which the applicant will be relieved of other academic or clinical responsibilities to have additional time for research, (2) the provision of adequate laboratory facilities, and equipment, and (3) opportunities for critical professional interaction with senior colleagues.

    - A letter of support from the mentor describing his or her commitment to the training/career development/mentorship of the applicant.

      The mentor should also include the following in his or her letter of support:
      - A description of the applicant's potential as a future breast cancer researcher;
      - A description of the mentor's interaction in training the candidate;
      - A description of the training environment;
      - A brief overview of the mentor's clinical research program and plans to incorporate the applicant's training program into this research;
      - A description of the mentor's previous experience in training fellows, residents, doctoral students, etc.
      - A brief overview of research being performed under the mentor's direction;
      - Information on how the mentor can assist in training the applicant for a career in breast cancer research;
      - A brief description of the group's resources to demonstrate the adequacy of available support for the trainee and the project (specific details on existing support should be covered in the Existing/Pending Support section; see item 15 above).

    Note: Administrative documentation **will not** be accepted separately from the electronic submission. All documents or letters must be signed and then scanned into the proposal prior to submission.

Proposals lacking required administrative documentation may be considered noncompliant and thus may not be forwarded for review (see Appendix B, part 22).

18. Detailed Cost Estimate – See Appendix B, part 18 and Appendix F.
The performance period for these awards will be 5 years. The total support that can be requested over the life of the award is $700,000 inclusive of direct, indirect, and medical school debt reduction costs.

Salary support can be requested for up to 60% of the PI's salary and for up to 50% of a key support person's salary (for example, a research nurse or a data manager) for 3 years plus indirect costs as appropriate. No salary support will be offered for years 4 and 5 of this award. Training awards frequently have a different institutional indirect charge. Physician-Scientist Training Award applicants are encouraged to check with their institution concerning indirect costs. Direct costs can cover only salary support and travel to scientific meetings. Funds for other research expenses must be provided from another resource (e.g., a grant to the mentor). The amount allotted for travel is $1,800 per year to attend scientific/technical meetings. In addition, funding should be requested for a one-time, 3½-day meeting to disseminate the results of Department of Defense-sponsored research. Applicants are asked to budget for this meeting in year 2 of the Detailed Cost Estimate Form.

In addition, the Physician-Scientist Training Award offers a medical school debt reduction incentive. Up to $40,000 per year (representing no more than the actual loan repayments made by the PI during the year) can be requested for repayment of qualifying medical school education loans over the 5-year performance period of the award. Upon completion of the 5-year commitment to clinical breast cancer research, an additional payment will be made to cover the remainder of the medical school education loan(s), up to a total of $200,000 for loan repayment over the 5-year period. For example, a PI with a total medical school education loan of $100,000 principal and annual payments of $18,000 would receive $18,000 per year for the 5 years of the award. Just prior to the end of the performance period, an additional payment equal to the remaining debt of the original loan would be made. The institution to which the award is made will be reimbursed for payments made by the applicant for his or her current medical school loans. Qualifying loans include funds borrowed from the Government, academic institutions, or commercial lenders for medical school tuition expenses at an accredited U.S. medical or osteopathic school, additional educational expenses (e.g., textbooks, supplies, fees), and reasonable living expenses. Certain loans do not qualify for repayment under this award, including loans from individuals or any loan that has been consolidated with that of another individual and loans already being repaid from another award source. Include the total amount of eligible medical school education loans and yearly payments in the budget estimate. Additional loan documentation will be required and final decisions regarding qualification of a loan for repayment will be made at the time of award negotiation.

19. Instruments – See Appendix B, part 19.

20. Publications and/or Patent Abstracts – See Appendix B, part 20.

21. Proposal Submission – See Appendix B, part 21.

22. Submission Deadline – See Appendix B, part 22.
    Please note that one electronic PDF version of your proposal must be uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet no later than **11:59 p.m. (applicant's local time) June 12, 2002. Submission of a proposal after the deadline may be grounds for proposal rejection.**

23. Regulatory Compliance and Quality Requirements – See Appendix B, part 23.
    The one-page Certificate of Environmental Compliance and one-page Principal Investigator Safety Program Assurance documents are to be submitted with the proposal. Additional documents related to Regulatory Compliance and Quality issues should be available on the CDMRP web site by April 2002. See Appendix B, part 23 for more details.

Principal Investigator: _____
Last Name *First Name* *MI*

Proposal Title: _____

_____

Physician-Scientist Training Award Proposal
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Proposal Body (6-page limit) ..... ___
Abbreviations (1-page limit) ..... ___
References (no page limit) ..... ___
Biographical Sketches (3-page limit each)
- PI ..... ___
- Mentor ..... ___
- Key Support Personnel ..... ___

Existing/Pending Support (no page limit) ..... ___
Facilities/Equipment Description (no page limit) ..... ___
Administrative Documentation (no page limit)
- List of all items included in Administrative Documentation section ..... ___
- Statement of Eligibility Form ..... ___
- Proof of citizenship or permanent resident status ..... ___
- Letter of institutional support ..... ___
- Letter of support from mentor ..... ___
- Letter describing mentor's clinical research program ..... ___

Detailed Cost Estimate (no page limit) ..... ___
Instruments (no page limit) ..... ___
Publications and/or Patent Abstracts (5-document limit) ..... ___
Certificate of Environmental Compliance ..... ___
Principal Investigator Safety Assurance ..... ___

STATEMENT OF ELIGIBILITY

Department of Defense
FY02 Breast Cancer Research Program
Physician-Scientist Training Award

Applicant's Name: _____

Title of Proposal: _____

I certify that the above-named investigator fulfills the following requirements to be considered for a Physician-Scientist Award and specifically meets all of the following criteria:

- Holds a medical degree, and
- Is in the last year of oncology graduate medical education or within the first 3 years of a faculty appointment.

Name of Official (*please print*):_____

Title:_____

Organization:_____

Signature of Official: _____ Date: _____

X. Innovator Awards

X-A. Innovator Awards

In its battle against breast cancer, the Breast Cancer Research Program (BCRP) is continuing the Innovator Award, a prestigious award introduced in Fiscal Year 2001 (FY01). The intent of this award is to provide accomplished and visionary scholars/investigators from the academic, government, and private sectors with the funding and freedom to pursue creative, potentially breakthrough research that could ultimately accelerate the eradication of breast cancer.

This award is designed to encourage the most creative individuals in all areas of research to pursue innovative and novel approaches that may significantly contribute to the conquest of breast cancer. The primary criteria for making these awards will be the record and potential for accomplishment of the applicant rather than the merits of a specific research project. Experience in breast cancer research is not required; applicants can be new to the field of breast cancer research. Established breast cancer researchers with a history of innovative insights who want to further and expand their current breast cancer research initiatives are also invited to apply.

Recipients of the Innovator Award may be scholars in all areas of investigation including the biological and physical sciences, computer sciences, social sciences, philosophy, economics, the humanities, and engineering. The BCRP's goal is to recognize talented individuals rather than projects, and the central feature of the award is the singular contribution(s) that the recipient will make to the cure and/or prevention of breast cancer.

The Innovator Award will provide recipients with the flexibility to explore exciting directions in breast cancer research. For example, recipients may use the award to establish multidisciplinary collaborations, redirect their careers to innovative breast cancer research, and/or establish research efforts at new, intellectually stimulating environments. The preceding list is meant only to provide examples for use of the award and should not be considered comprehensive. A traditional research proposal is not expected; however, the candidate is required to submit an essay that addresses several areas including his or her area(s) of focus and how he or she will use the award to pursue creative breast cancer investigations.

This award is designed to facilitate creative thinking and imaginative application of ideas to the field of breast cancer by investigators who have a prior history of creativity and innovation in their respective fields and careers. It is expected that the candidate will commit a minimum of 50% of his or her full-time professional effort to breast cancer research during the period of this award. Innovator Award recipients will meet annually with the Integration Panel (IP) and Program Staff for the purpose of open communication and mutual benefit and will report progress as an oral presentation and/or written summary.

Approximately $9M will be available for Innovator Awards, but this could be increased depending on the quality of the applications. Funding for Innovator Awards can be requested for a maximum of $3M for a period of up to 4 years, inclusive of direct and indirect costs. Examples of possible uses for the award include project-related expenses such as salaries, travel, support of multidisciplinary collaborations, seminars, conferences, workshops, training, equipment, and supplies.

For complete application requirements, please refer to Section X-D. Additional guidance for application preparation may be gained by reviewing the review criteria listed in Section X-B.1.

Submission of the same research project to the FY02 BCRP under different award mechanisms will not be allowed, and all such duplicate submissions may be administratively withdrawn. This includes submissions under different award mechanisms from different Principal Investigators (PIs). The Government reserves the right to reject any proposal.

X-B. Application Evaluation

Due to the unique nature of the award, the review process described in Section I-C will be modified for the Innovator Award. Applications will be evaluated using a two-tiered process.

X-B.1. Peer Review

The first tier peer review will be conducted by a multidisciplinary panel of knowledgeable and visionary scholars and researchers who are representatives from academia, government, industry, and breast cancer consumer organizations. The primary responsibility of the first tier reviewers will be to rank the applications received and make recommendations for awards to the IP.

The following criteria will be used to evaluate and compare the applications during the first tier of review:

- **Candidate:** Have the candidate's past and current endeavors had groundbreaking impact in his or her field? Does the application reflect creativity and innovative thinking and support the likelihood that the candidate would have a significant impact on breast cancer? Does the candidate's record of accomplishment demonstrate outstanding ability as an independent and visionary scholar/investigator?

- **Relevance and Impact:** Does the applicant's vision for the tenure of the award address an important problem(s) in breast cancer? Is the work demonstrably creative and does it have the potential to significantly impact the prevention, detection, diagnosis, treatment, and/or management of breast cancer?

- **Vision and Ideas:** Does the candidate communicate a clear vision of what he or she hopes to accomplish during the tenure of the award? Are the concepts and ideas original and innovative? Do the candidate's ideas reflect innovative thinking and does he or she present a clear and compelling argument for how this award will be used to pursue creative (potentially groundbreaking) breast cancer research?

- **Environment:** Is there evidence that the environment will facilitate and encourage the proposed work? Are the necessary resources available, or does the candidate have a plan for access to or creation of the needed resources?

X-B.2. Programmatic Review

The second tier will be programmatic review. Programmatic review will be accomplished by members of the IP, composed of scientists, clinicians, and consumer advocates who are expert in the area of breast cancer research and/or advocacy (see Sections I-B and I-C.2). The complete award application will be forwarded for second tier review. The second tier of review will take programmatic relevance and program portfolio balance into consideration.

X-C. Letter of Intent

All applicants considering submission of an Innovator Award application in response to this program announcement are ***required*** **to submit an electronic Letter of Intent no later than 11:59 p.m. (applicant's local time) May 30, 2002.** This form can be found on the Congressionally Directed Medical Research Programs (CDMRP) web site at http://cdmrp.army.mil/funding/02bcrp2.htm.

X-D. Application Preparation

Please use the following information specific for Innovator Awards in the preparation of your application and refer to Appendix B as appropriate. Please note that the required essay is limited to **5 pages**, inclusive of any figures, tables, graphs, and photographs. **Applications exceeding specified page limits may be administratively withdrawn by the Government prior to peer review.**

Ensure that one electronic Portable Document Format (PDF) version of your application, which will serve as the official application submission, is uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet no later than **11:59 p.m. (applicant's local time) June 13, 2002.** Applicants are required to submit the Proposal Information prior to upload/submission of the proposal. Applicants are encouraged to begin this part of the submission process early and submit their Proposal Information at least 2 weeks prior to the submission deadline.

Applicants unfamiliar with the preparation and submission of PDF files are encouraged to acquire the software and learn the process well before the submission deadline.

1. Who May Apply
   Eligible institutions include for-profit, non-profit, public, and private organizations. Examples include universities, colleges, hospitals, laboratories, publicly or privately held companies, and agencies of local, state, and federal governments. All individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by or affiliated with an eligible institution.

   Individuals not affiliated with an institution may apply for the Innovator Award. However, if the application is recommended for funding, they will be required to submit documentation for a determination of responsibility to be made by the U.S. Army Medical Research Materiel Command. Such documentation may include, but is not limited to, information on time management, project management, and financial accountability.

   Due to the unique nature of the award, if an Innovator Awardee should move to a new institution during the tenure of the award, the new institution will be designated as the recipient institution for the remaining award amount.

2. Application Acceptance Criteria – See Appendix B, part 2.
   Please note that the same acceptance criteria are applied to Innovator Award applications as to proposals for other award mechanisms.

3. Proposal Information – See Appendix B, part 4 and Appendix C.

4. Title/Referral Page – See Appendix B, part 5.

5. Table of Contents – See Appendix B, part 6.
   Use the table of contents at the end of this section in your application submission. This table of contents should be used as a guide for assembling all required components of the application. Number all pages consecutively at the bottom center, beginning with the Title/Referral Page. Provide a header on every page of the application that includes the PI's name (last name, first name, middle initial) and proposal log number (this number will be automatically provided when a draft of the Proposal Information is saved; see Appendix C).

6. Checklist for Application Submission – See Appendix B, part 7.

7. Application Abstracts
   Both a 1-page technical abstract and a 1-page lay (nontechnical) abstract summarizing the application essay (see item 8 below) are required. Each application abstract page should contain the title of the application and the name of the PI. Abstracts must be submitted as part of the application. **Do not include figures or tables in either abstract.**

   Sample abstracts for other award mechanisms are included in Appendix D. Please note that the technical abstract for Innovator Award applications is not required to follow the

structured format described in Appendix B, part 8.

The lay abstract is intended to communicate the purpose of, and rationale for, the study to the non-scientific community. It should be composed in a way to make the objectives and rationale for the application understandable to non-scientifically trained readers. The lay abstract should not duplicate the technical abstract.

Abstracts of all funded applications will be posted on the CDMRP web site at http://cdmrp.army.mil. Thus, proprietary or confidential information should not be included in the abstracts.

8. Application Essay
The candidate must submit an essay that is limited to **5 pages,** inclusive of figures, tables, graphs, and photographs, if used.

The content of the essay should address the following points:

- **Current Status of Breast Cancer Research:** Describe your views of the major research problems/barriers in breast cancer research that must be solved to accelerate progress and hasten the eradication of breast cancer.

- **Your Vision of the Future:** What do you see as the critical approaches, discipline combinations, etc., that will most likely produce breakthrough thinking and discoveries to ultimately solve the major problems/barriers that you have defined?

- **Your Specific Ideas:** Summarize some of the key examples of specific innovative ideas, hypotheses, research programs, etc. that you envision pursuing under the auspices of this award. Explain why/how your ideas may challenge current assumptions and ultimately produce significant progress.

- **Preparation for This Award:** Explain why/how your past training and experience qualifies you to receive this award. Give some examples of breakthrough creative thinking and/or experimentation in your past work that demonstrates your abilities as an innovator. How do you think your past publications, patents, other achievements, etc., reflect your capabilities as an innovator?

9. Abbreviations – See Appendix B, part 12.

10. References – See Appendix B, part 13.

11. Curriculum Vitae
    Applicants should submit their complete curriculum vitae including employment, experience, honors, and a list of publications and patents. The publication list should exclude abstracts and should distinguish which publications are peer reviewed. On the curriculum vitae, the candidate should indicate up to three publications he or she considers most significant to the proposed work. Please note that the acceptance criteria in Appendix B, part 2 will apply to the curriculum vitae. There is no page limit for the curriculum vitae. If the PI chooses to include biographical information on key collaborators as part of the Innovator Award application, the Biographical Sketch Form should be used (see Appendix B, part 14 and Appendix E); curriculum vitae of collaborators should not be included.

12. Existing/Pending Support – See Appendix B, part 15.

13. Facilities/Equipment Description – See Appendix B, part 16.

14. Administrative Documentation – See Appendix B, part 17.
    In addition to the documentation described in Appendix B, provide the following items in the Administrative Documentation section of the application submission:

    - Letter of institutional support for the candidate's receipt of an Innovator Award, if applicable, as reflected by (1) the extent to which the applicant will be relieved of academic or administrative responsibilities and (2) permission to use institutional resources as needed.

    - Three letters of nomination addressing the past and current creativity and innovation of the applicant should be provided.

    Note: Administrative documentation **will not** be accepted separately from the electronic submission. All documents or letters must be signed and then scanned into the application prior to submission.

    Applications lacking required administrative documentation may be considered noncompliant and thus may not be forwarded for review (see Appendix B, part 22).

15. Cost Estimate – See Appendix F.
    Please complete the second page of the Detailed Cost Estimate Form (Budget for Entire Proposed Period of Support) from Appendix F. The Detailed Budget for Initial Budget Period (first page) and the Budget Justification (third page) are not required with the application. Funding for Innovator Awards can be requested for a maximum of $3M for a period of up to 4 years, inclusive of direct and indirect costs. Direct costs can include (but are not limited to) any project-related expenses such as salaries, travel, support of multidisciplinary collaborations, seminars, conferences, workshops, training, equipment, and supplies. Funds for the support of "to be named" trainees may be requested. Funds should be requested for an annual meeting of recipients of the Innovator Award with the IP

and Program Staff. In addition, funding should also be requested for a one-time, 3½-day meeting to disseminate the results of Department of Defense (DOD)-sponsored research. Applicants are asked to budget for this meeting in year 2 of the Detailed Cost Estimate Form.

For all DOD-funded research involving human subjects, medical care for research-related injuries must be provided at no cost to the subject. Many institutions and states provide for this medical care as part of their liability insurance. If not, investigators should plan on budgeting for such costs. The institution business office and U.S. Army Medical Research Acquisition Activity can assist applicants with budgeting for this requirement. See Appendix F for more details.

16. Instruments – See Appendix B, part 19.

17. Publications and/or Patent Abstracts – See Appendix B, part 20.

18. Application Submission – See Appendix B, part 21.

19. Submission Deadline – See Appendix B, part 22.
    Please note that one electronic PDF version of your application must be uploaded/submitted by an authorized Administrative Representative of your organization's Sponsored Programs Office (or equivalent) through the Internet no later than **11:59 p.m. (applicant's local time) June 13, 2002. Submission of an application after the deadline may be grounds for application rejection.**

20. Regulatory Compliance and Quality Requirements – See Appendix B, part 23.
    The one-page Certificate of Environmental Compliance and one-page Principal Investigator Safety Program Assurance documents are to be submitted with the proposal. Additional documents related to Regulatory Compliance and Quality issues should be available on the CDMRP web site by April 2002. See Appendix B, part 23 for more details.

    Please note that any research involving human or animal use must be approved if the application is recommended for funding.

Principal Investigator: _____
Last Name *First Name* *MI*

Proposal Title: _____

_____

Innovator Award Application
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Administrative Documentation (no page limit)
- List of all items included in this section ..... ___
- Letter of institutional support ..... ___
- Letters of nomination ..... ___
- Letters of support from collaborating individuals and/or institutions ..... ___

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